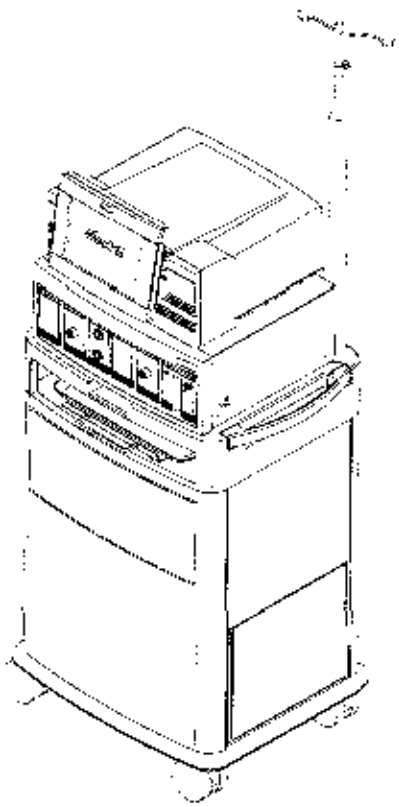

storz

MILLENNIUM™

MICROSURGICAL SYSTEM

Owner's Manual

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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Revision: C
110-017-065

Date Effective: September 1997

Preface

Table of Contents

Preface

	Table of Contents	i
	Manual Concept	vii
	Precautions	ix
1	**Quick Reference**	1–1
1.1.	System Description	1–1
	System Components	1–2
	Peripherals	1–4
1.2.	Turning on Your System	1–5
1.3.	Anterior Segment Example	1–6
	Setting Up Your System	1–7
	Ultrasound Calibration	1–8
	Using Your System in Surgery	1–9
	Ultrasound Set–up	1–9
	Irrigation/Aspiration Set–up	1–10
	Anterior Vitrectomy Set–up	1–11
	Surgical Procedure Conclusion	1–12
2	**User Interface**	2–1
2.1.	Basic Button Operations	2–1
2.2	User Interface Concepts	2–4
	Screen Layout	2–4
	Anterior Surgical Mode	2–6
	Posterior Surgical Mode	2–7
2.3.	User Interface Screens	2–8
2.4	Foot Controller	2–9

	Basic Button Operation	2–10
	Linear Control	2–12
	Single Linear Control	2–12
	Dual Linear Control	2–12
3	**Customizing Your System**	3–1
3.1.	Mode Programming	3–1
	Create a New Setup	3–1
	Modifying an Existing Setup	3–3
	Customizing Mode Settings	3–5
	Customizing Footpedal Settings	3–6
	Customizing the Mode Sequence	3–7
	Customizing Audio Control	3–8
	Customizing Language Setting	3–11
3.2.	Saving Your Personal Settings	3–12
3.3.	Transferring Personal Settings from One System to Another	3-13
4	**Advanced Operation**	4–1
4.1.	Computer Unit	4–1
4.1.	Screen Drape Installation	4–3
4.2.	Base Unit	4–4
4.3.	Instrumentation Cart	4–5
4.4.	IV Pole	4–6
4.5.	Remote Control	4-7
4.6.	IAV Venturi Module	4–8
	Irrigation Aspiration Mode	4–8
	Irrigation	4–8
	Irrigation–Aspiration	4–8
	Capsule Polish	4–9

Viscoelastic Removal .....
Linear Vacuum .....
Reflux .....
Foot Control of Irrigation/Aspiration .....
Vacuum Response .....
Venturi Irrigation/Aspiration Set–up And Use. ....
Vitrectomy Mode. .....
Foot Control Of Anterior Vitrectomy Mode. .....
Foot Control Of Posterior Vitrectomy Mode. .....
Operating Modes. .....
Anterior Vitrectomy Set–up And Use – Venturi. ...
Posterior Vitrectomy Set–up and Use – Venturi. ...
4.7. Ultrasound Module. .....
Ultrasound Module Description. .....
Pulsed Ultrasound Mode. .....
Irrigation/Aspiration in Ultrasound Mode: .....
Ultrasound Mode .....
Footpedal Operation In Anterior Single Linear Ultrasound Mode .....
Dual Linear With Yaw Aspiration .....
Footpedal Operation In Anterior Dual Linear Ultrasound Mode .....
Footpedal Operation in Posterior Ultrasound Mode
Linear Vacuum .....
Fixed Vacuum .....
Dual Linear Segment Removal .....
Dual Linear Sculpt .....
Segment Removal .....

	Sculpt	4 32
	Phacoemulsification Set Up Venturi	4–33
	Phacoemulsification Operation	4 35
	Phacofragmentation Handpiece Set Up Venturi	4 38
	Phacofragmentation Operation	4–40
4.8.	Coagulation Module	4–43
	Fixed Coagulation Set–up And Use	4 44
	Linear Coagulation Set Up and Use	4–46
4.9.	Illumination Module	4–18
	Illumination Setup and Use	4 48
4.10.	Scissors/Air Module	4–50
	Scissors/Forceps	4–50
	Scissors Operation	4 50
	Scissors Set–up	4–51
	Air/Fluid Exchange	4–53
	Air/Fluid Exchange Operation	4–53
	Air/Fluid Exchange Set–up	4 54
	Bottle Infusion	4–56
	Bottle Infusion Set up	4–56
4.11.	Viscous Fluid System Module	4 58
	Viscous Fluid System Setup and Use	4–60
5	**Cleaning and Sterilization Requirements**	5–1
5.1.	Computer Unit, Base Unit and Cart	5–1
5.2.	Bipolar Coagulation Accessories	5 2
5.3.	Irrigation Handpiece and Irrigation/Aspiration Handpiece	5–3
	Handpiece Cleaning Instructions	5 3
	Irrigation and I/A Handpiece Sterilization	5 5

5.4.	Phacoemulsification Handpiece	5–6
	Handpiece Cleaning Instructions	5-6
	Phacoemulsification Handpiece Sterilization	5-10
5.5.	Phacofragmentation Handpiece	5–11
	Handpiece Cleaning Instructions	5–11
	Phacofragmentation Handpiece Sterilization	5-14
5.6.	Microscissors Handpiece	5-15
	Tip Storage	5–15
5.7.	ErgoTec ® Vitreoretinal Instruments.	5–16
	Sterilization:	5-17
	Storage:	5–17
5.8.	Special Instructions for United Kingdoms.	5–18
6	**Unpacking and Set-up**	**6–1**
6.1.	Unpacking Instructions.	6–1
6.2.	Connections and Setup.	6-1
6.3.	Adding or Replacing Modules.	6–8
7	**Maintenance, Service and Warranty**	**7–1**
7.1.	System Checkout	7-1
7.2.	User Troubleshooting	7-1
7.3.	System Messages	7–2
7.4.	Lamp Replacement	7–10
7.5	Fuse Replacement	7-12
7.6.	Service Information	7-14
	Technical Assistance.	7–14
	Returning Modules to Storz.	7–15
7.7.	Environmental Protection	7-16
7.7.	Warranty Information	7-16

8	**Specifications**	8–1
8.1.	Environmental and Physical Specifications	8–1
	Environmental Specifications	8–1
	Physical Specifications	8–2
	Equipment Classifications	8–2
8.2.	Ophthalmic Module Specifications	8–3
	Air/Fluid Exchange Specifications	8–3
	Scissors/Forceps Specifications	8–4
	Coagulation Module Specifications	8–5
	Illumination Module Specifications	8–6
	Irrigation, Venturi Aspiration and Vitrectomy Module Specifications	8–7
	Ultrasound Module Specifications	8–9
	IV Pole Specification	8–10
	Computer Unit Specifications	8–11
	Remote Control Unit Specifications	8–12
	Foot Controller Specifications	8–13
Index		Index–i

Manual Concept

Storz designs manuals to give you the information you need when you need it, and we don't want you to have to search to find it. We periodically conduct focus groups on our products, and we have used the results of these focus groups to develop a manual which we hope you will find useful and informative.

This manual is organized so that in the first chapter you will find enough information to quickly get up and running, and to answer general questions about the ***Storz Millennium™ Microsurgical System***. We have added plenty of pictures so concepts can be grasped quickly. Be sure to read chapter 2 to become familiar with the graphical user interface and the foot controller. These are your connections to operating the system. You will find in chapter 3 information on how to customize the system to suit your particular needs. In chapter 4 you will find detailed information about each module function and feature, how to set up the module and its associated disposables, and how to interact with each module. Chapter 5 gives you cleaning and sterilization information. These chapters are meant to serve as a reference to questions of a more technical nature. Chapters 6 through 8 contain information that you may rarely need, such as unpacking, installing modules, system checkout, meanings of error messages, service information, and system specifications.

On the following pages you will find a summary of the precautions that should be observed when using this equipment. Each precaution shows the page number where it appears near the applicable instruction. For safety's sake, please heed these precautions.

We hope that this manual meets your needs. The Technical Publications Department would appreciate any comments you care to share with us.

SYMBOLS AND NOTES

The following are general definitions of the symbols and precautions used on this equipment and in this manual.

This symbol indicates that it is necessary for the user to refer to the appropriate instruction.

DANGER: "Danger" calls attention to an operating procedure, practice, or condition, which if disregarded or incorrectly performed, could result in eminent death or serious injury.

WARNING: "Warning" calls attention to an operating procedure, practice, or condition, which if disregarded or incorrectly performed, could result in injury to personnel and/or patients.

CAUTION: *"Caution" calls attention to an operating procedure, practice, or condition, which if disregarded or incorrectly performed, could result in damage to the product and/or equipment.*

NOTE: *"Note" calls attention to an operating procedure, practice, or condition providing essential information.*

Precautions

DANGER: EXPLOSION HAZARD. Do not use in the presence of flammable anesthetics, disinfectants, aerosol sprays, or in an oxygen rich atmosphere. 1–5, 4–1, 6 1

WARNING: Implantable defibrillators present a risk of injury if triggered by a fibrillatory event during intraocular surgery, due to involuntary motion by the patient. Patients being considered for intraocular procedures must be questioned to determine if they have such a device and, if so, the defibrillator manufacturer must be consulted to determine the appropriate action. 1–1

WARNING: Manufacturers of implantable defibrillators recommend that these devices be temporarily disabled when using bipolar cautery on patients with implants. The surgeon should determine if the patient has such a device and consult the manufacturer for appropriate actions. 1–2

WARNING: Manufacturers of implantable defibrillators recommend that these devices be temporarily disabled when using phacoemulsification or phacofragmentation systems on patients with these implants. This is especially important when using pulsed phaco modes of operation. Although the implanted devices are designed to reject electromagnetic interference, and Storz microsurgical equipment is designed to minimize such interference, a chance interaction cannot be ruled out. Patients should be questioned to determine if they have such an implant and, if so, the manufacturer should be consulted to determine the proper course of action. 1 3

WARNING: Use only handpieces, cables, and accessories designated by Storz Instrument Company for use with this system. 1 4

WARNING: This system should only be operated by personnel who have been trained and qualified to use this system. 1 5

WARNING: ***For optimum aspiration and reflux performance, the Storz Millennium™ Microsurgical System cassette aspiration port must be placed at the same level as the patient's eye, with no more than 7 cm (3 in) differential.*** 4 9, 4 12, 4 14, 4 18, 4 23, 4 29, 4 33, 4 38

WARNING: ***Assure the handpiece and accessories are sterilized before use as specified.*** 4 12, 4 33, 4 38, 4 44, 4 46

WARNING: ***A loose needle may lead to improper calibration and could cause shedding of metal fragments into the eye.*** . . . 4–33, 4 38, 4–49, 4–57, 4–59.

WARNING: ***Allow 20 minutes for the handpiece to cool after sterilization before it is used.*** 4 38, 5 2, 5 6, 5 10, 5 14, 5 15, 5 17

WARNING: ***Check the coagulation power level when changing between extraocular and intraocular cauterization.*** 4 43

WARNING: ***Use only bipolar handpieces and cables designated by Storz Instrument Company for use with this system.*** . . . 4–43

WARNING: ***Care should be taken to avoid concentrating the output of the illumination module on a small area of the retina for unnecessarily prolonged periods of time due to the potential for phototoxicity.*** 4 48

WARNING: ***Disconnect AC power before cleaning the cabinet.*** 5–1

WARNING: The coagulation accessories should not be sterilized using a cold soaking solution. 5–2

WARNING: Do not cold sterilize the instrument. The sterilizing solution may not be flushed out prior to surgery and could be flushed into the eye, resulting in serious eye injury. . . 5–3, 5–10, 5–12

CAUTION: *Electromagnetic interaction between the phacoemulsification or phacofragmentation handpieces and an implanted cardiac pacemaker is unlikely, but cannot be ruled out. Patients should be questioned to determine if they have such an implant and, if so, the manufacturer of the implant should be consulted to determine the proper course of action.* 1–1

CAUTION: *Manufacturers of cardiac pacemakers advise against use of bipolar cautery devices on patients with such implants. When conducting surgery on such a patient, a battery-powered thermal cautery may be used, or the manufacturer of the pacemaker should be consulted to determine appropriate steps to take in order to use the bipolar function.* 1–2

CAUTION: *Never place an irrigation bottle or any other containers of liquid on the computer unit.* 4–2

CAUTION: *The Remote Control is* ***not*** *waterproof.* 4–1

CAUTION: *Allow 20 minutes for the handpiece to cool after sterilization before it is used. Electrical connector must be completely dry before connecting to module.* . . 4–33, 4–49, 4–57

CAUTION: *Do not touch the handpiece needle at any time while ultrasound power is operating.* 4–40

CAUTION: *To preserve the cabinet finish, avoid the use of abrasive cleaners. If possible, clean spots before they dry.* . . . 5–1

CAUTION: *Use only warm (30° C to 40° C – 85° F to 105° F) distilled or deionized water to flush the handpiece.* 5–4, 5–8, 5 -11, 5 15, 5 16

CAUTION: *Before each use, the handpiece and power cord should be inspected for damage (e.g. nicks, crimps, dents, exposed wires, etc.). If the handpiece is damaged, it should be immediately removed from service.* 5 10

CAUTION: *Do not rotate bezel up or down when removing or inserting. Pull directly up and then out.* 6–8

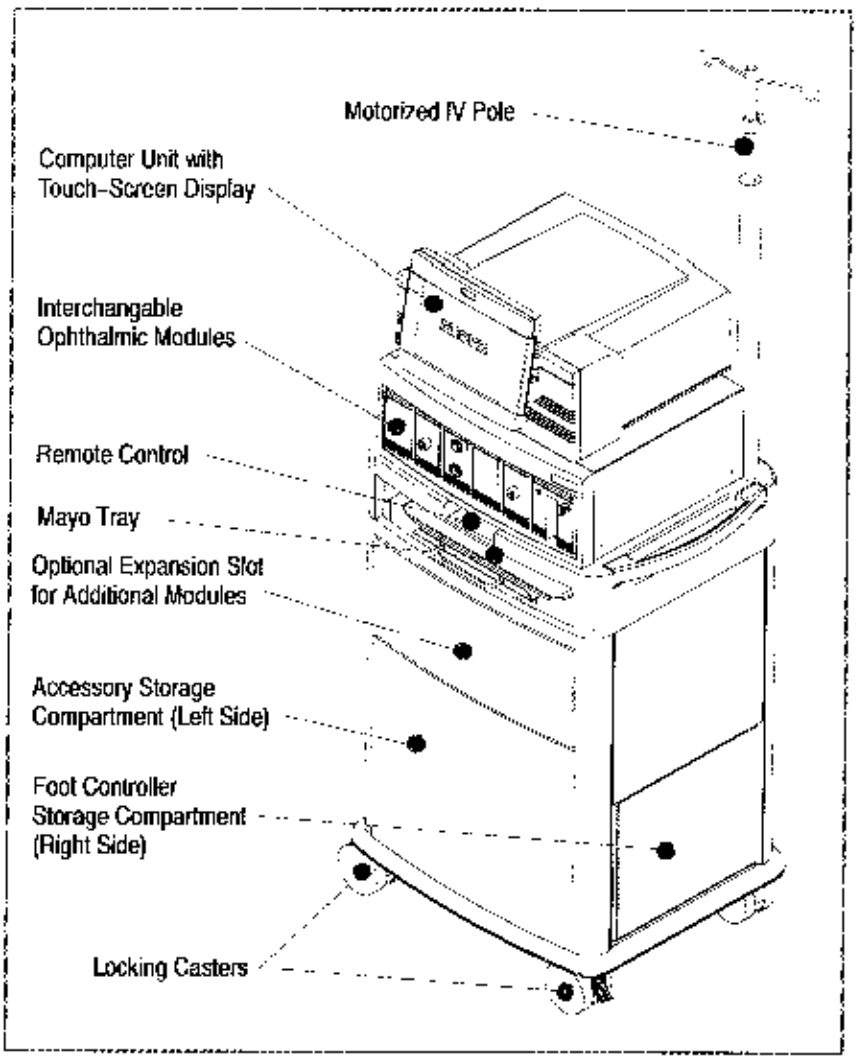
Chapter 1

Quick Reference

Chapter Objective: This chapter is for people who have used this type of ophthalmic microsurgical system before and who want to use the system without having to read large portions of the manual.

1.1. System Description

WARNING:
Implantable defibrillators present a risk of injury if triggered by a fibrillatory event during intraocular surgery, due to involuntary motion by the patient. Patients being considered for intraocular procedures must be questioned to determine if they have such a device and, if so, the defibrillator manufacturer must be consulted to determine the appropriate action.

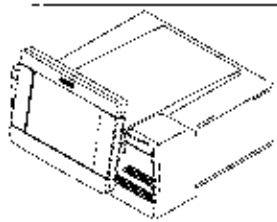


CAUTION:
Electromagnetic interaction between the phacoemulsification or phacofragmentation handpieces and an implanted cardiac pace maker is unlikely, but cannot be ruled out. Patients should be questioned to determine if they have such an implant and, if so, the manufacturer of the implant should be consulted to determine the proper course of action.

The *Storz Millennium™ Microsurgical System* is a modular design which enables it to be upgraded to take advantage of future technology. The system consists of a computer unit with display, a foot controller and a base unit which contains the surgical modules.

System Components

Computer Unit

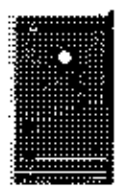


This is the main interface for the user to communicate with the microsurgical system. See page 4–1.

I/A and Vitrectomy Module *(Venturi)*

Provides vacuum levels from 0 to 550 mmHg generated by venturi pump. Irrigation on/off control is provided by a pinch valve. Vitrectomy operation supports Linear Cut Rate, and Fixed Cut Rate. See page 4–8.

Coagulation Module



Provides coagulation power in either Fixed or Linear modes. See page 4–43.

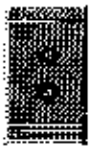
WARNING:
Manufacturers of implantable defibrillators recommend that these devices be temporarily disabled when using bipolar cautery on patients with implants. The surgeon should determine if the patient has such a device and consult the manufacturer for appropriate actions.

CAUTION:
Manufacturers of cardiac pacemakers advise against use of bipolar cautery devices on patients with such implants. When conducting surgery on such a patient, a battery–powered thermal cautery may be used, or the manufacturer of the pacemaker should be consulted to determine appropriate steps to take in order to use the bipolar cautery function.

1.1. System Description *(continued)*

System Components *(continued)*

WARNING:
Manufacturers of implantable defibrillators recommend that these devices be temporarily disabled when using phacoemulsification or phacofragmentation systems on patients with these implants. This is especially important when using pulsed phaco modes of operation. Although the implanted devices are designed to reject electromagnetic interference, and Storz microsurgical equipment is designed to minimize such interference, a chance interaction cannot be ruled out. Patients should be questioned to determine if they have such an implant and, if so, the manufacturer should be consulted to determine the proper course of action.

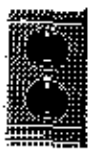


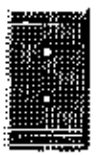
Ultrasound Module (Phacoemulsification, Phacofragmentation, or Elite)

Supports phacoemulsification and/or phaco fragmentation procedures in both linear and pulsed modes. See page 4–28.

Illumination Module

Provides two ports which can be operated simultaneously and controlled individually. See page 4–48.





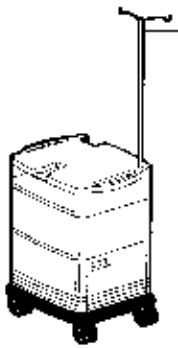
Scissors/Air Module

Supports electrical scissors and forceps functions in the following modes: Linear Cut Rate, Fixed Cut Rate. This module also provides air pressure for IOP. See page 4–50.

Foot Controller

Provides the main interface between the user and the microsurgical system for controlling most functions. See page 2–9.

Peripherals

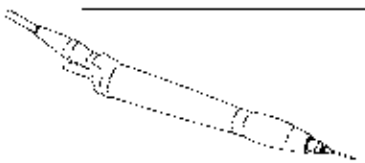


***Storz Millennium™ Microsurgical System* Cart with IV Pole**

See page 4–5

Remote Control

See page 4–7



Ultrasound Handpiece

See page 4–28

WARNING:
Use only handpieces, cables, and accessories designated by Storz Instrument Company for use with this system.

Coagulation Handpieces

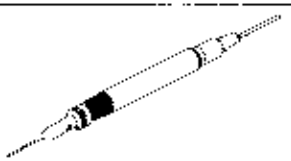
See page 4–43

Vitrectomy Cutter

See page 4–18

Scissors Handpiece

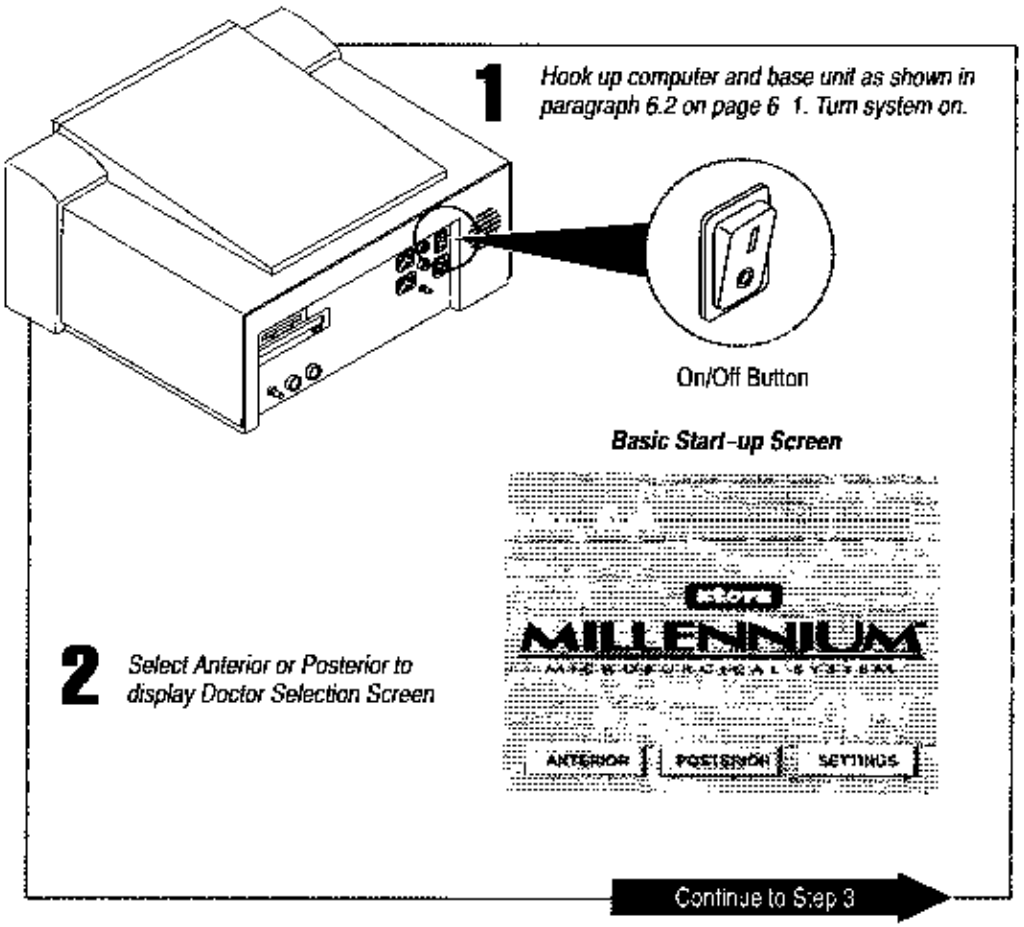
See page 4–50



1.2. Turning on Your System

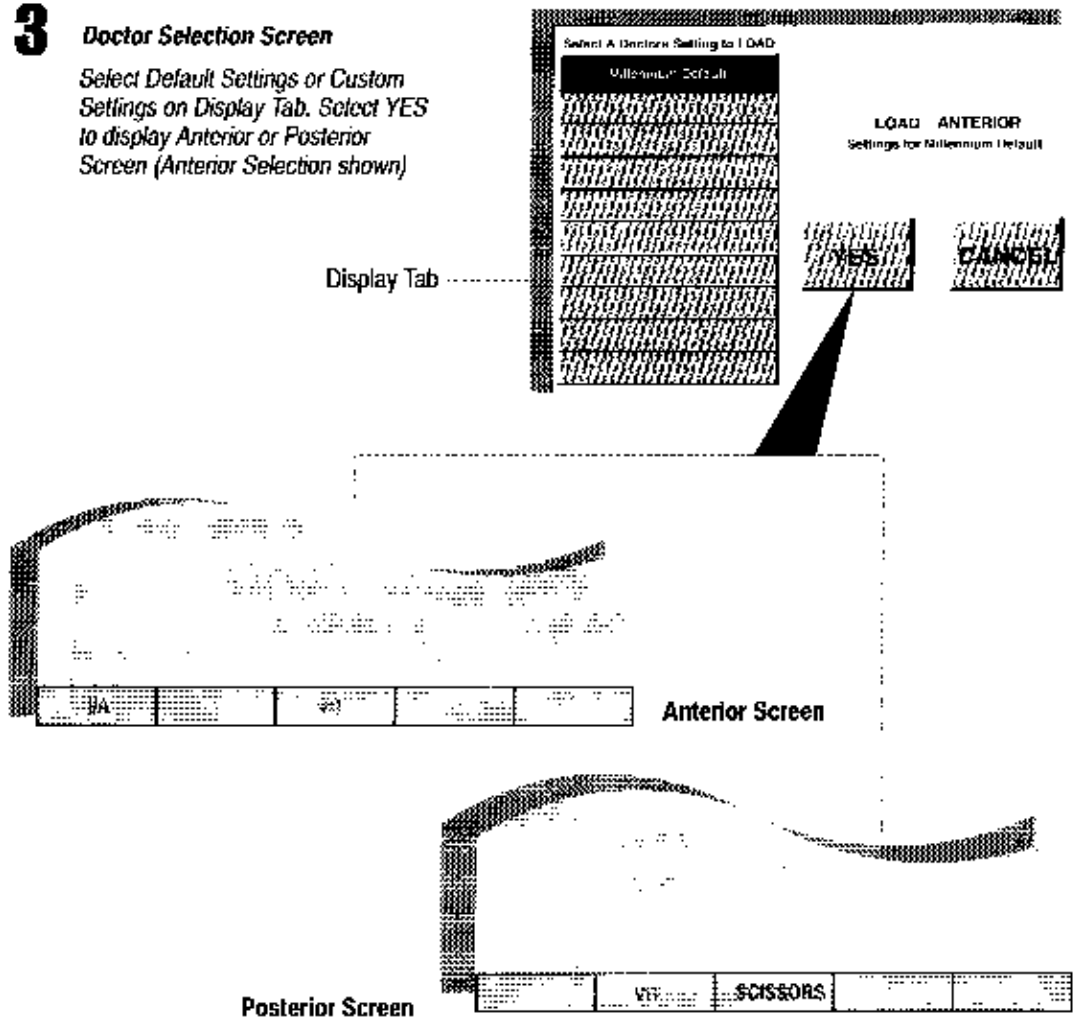
DANGER: EXPLOSION HAZARD. Do not use in the presence of flammable anesthetics, disinfectants, aerosol sprays, or in an oxygen rich atmosphere.

WARNING: This system should only be operated by personnel who have been trained and qualified to use this system.



3 ***Doctor Selection Screen***

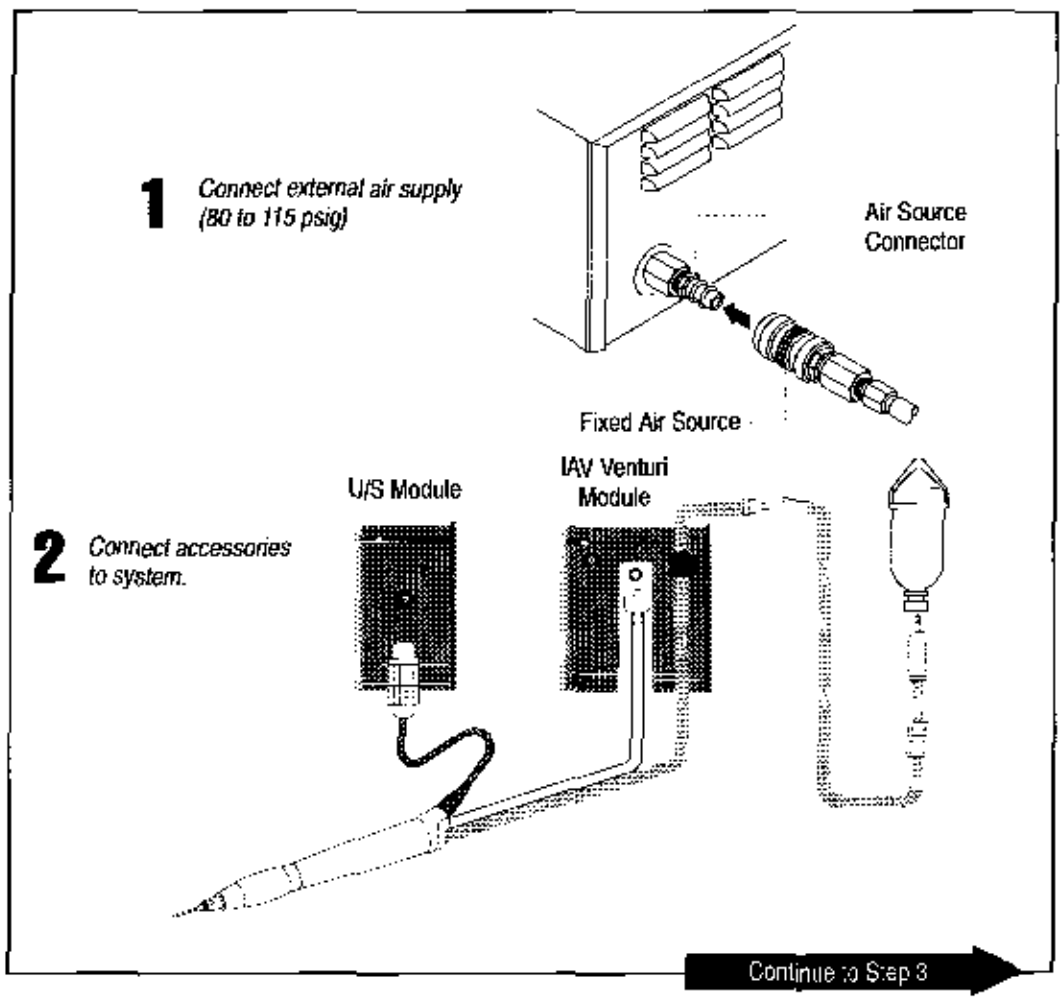
Select Default Settings or Custom Settings on Display Tab. Select YES to display Anterior or Posterior Screen (Anterior Selection shown)



1.3. Anterior Segment Example

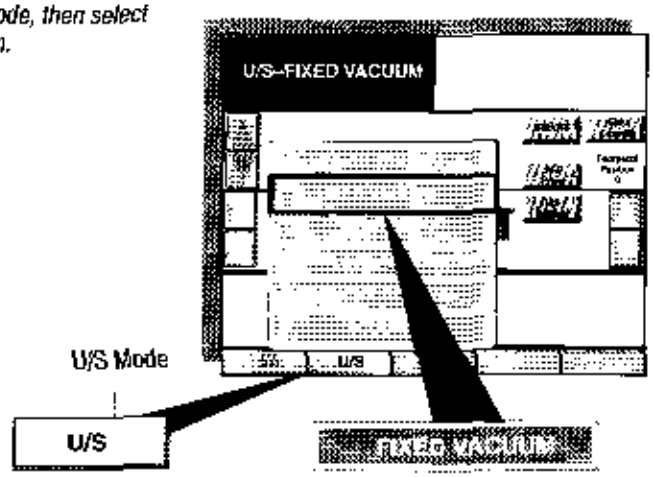
The following pages contain an overview for set up and use of your ***Storz Millennium™ Microsurgical System*** in a typical cataract surgery. It is presented here in a pictorial format, and is intended for use by someone already familiar with this type of system. For posterior segment surgery see chapter 4 for details.

Setting Up Your System

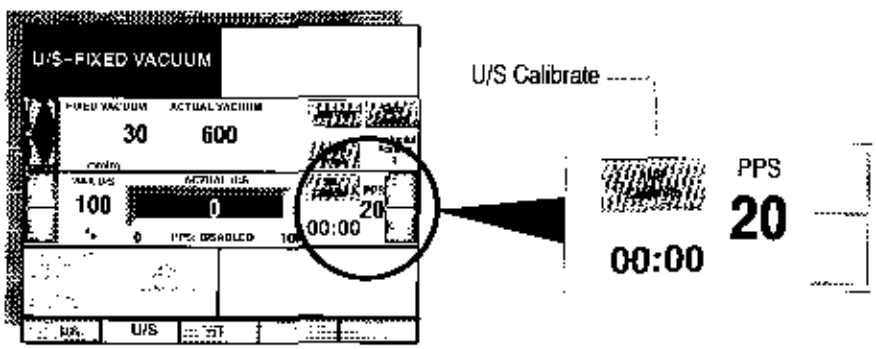

1 Connect external air supply (80 to 115 psig)
Air Source Connector
Fixed Air Source
U/S Module
IAV Venturi Module
2 Connect accessories to system.
Continue to Step 3

Ultrasound Calibration

3 *Select U/S Mode, then select Fixed Vacuum.*

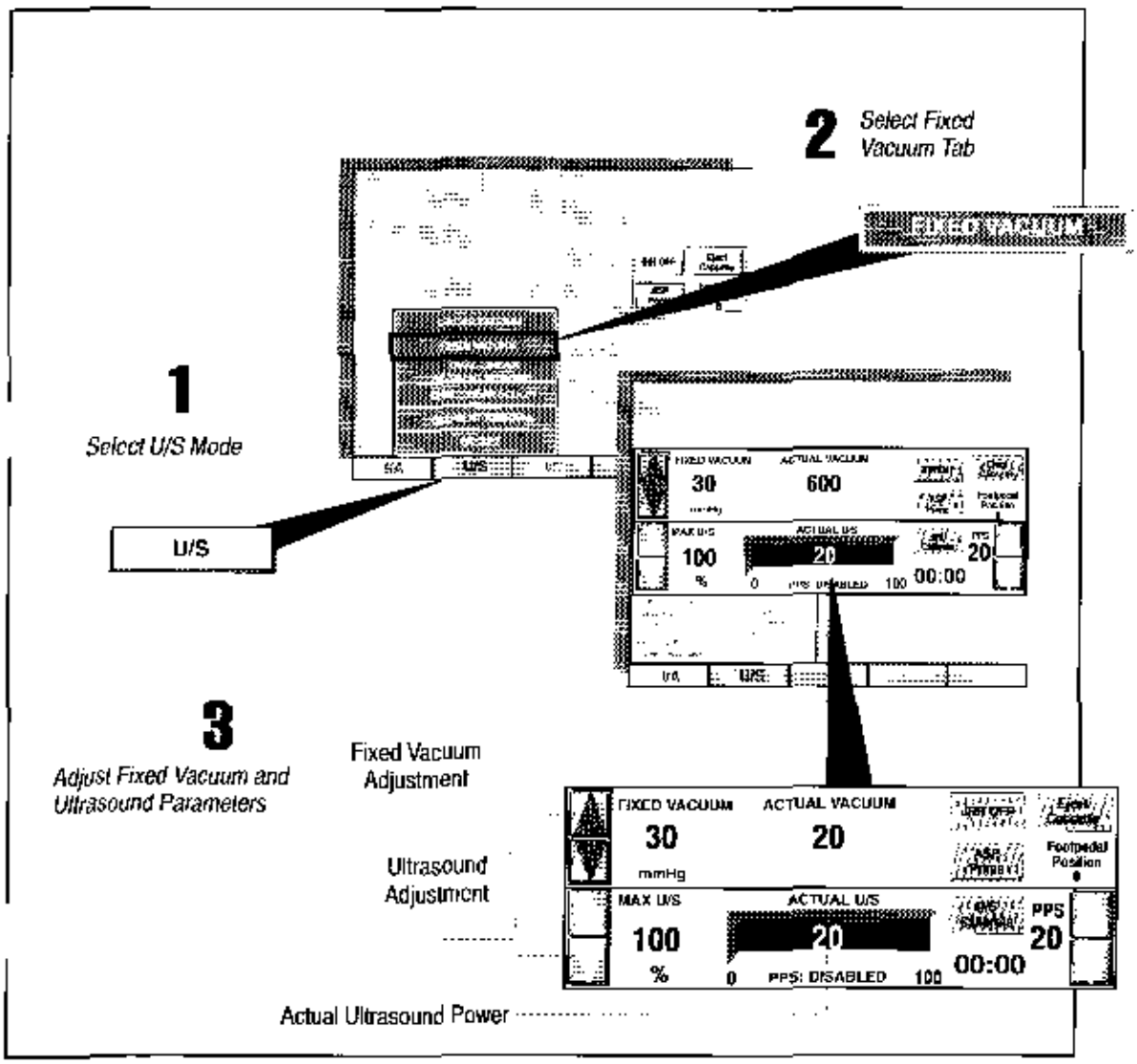


4 *Press U/S Calibrate button to calibrate handpiece.*

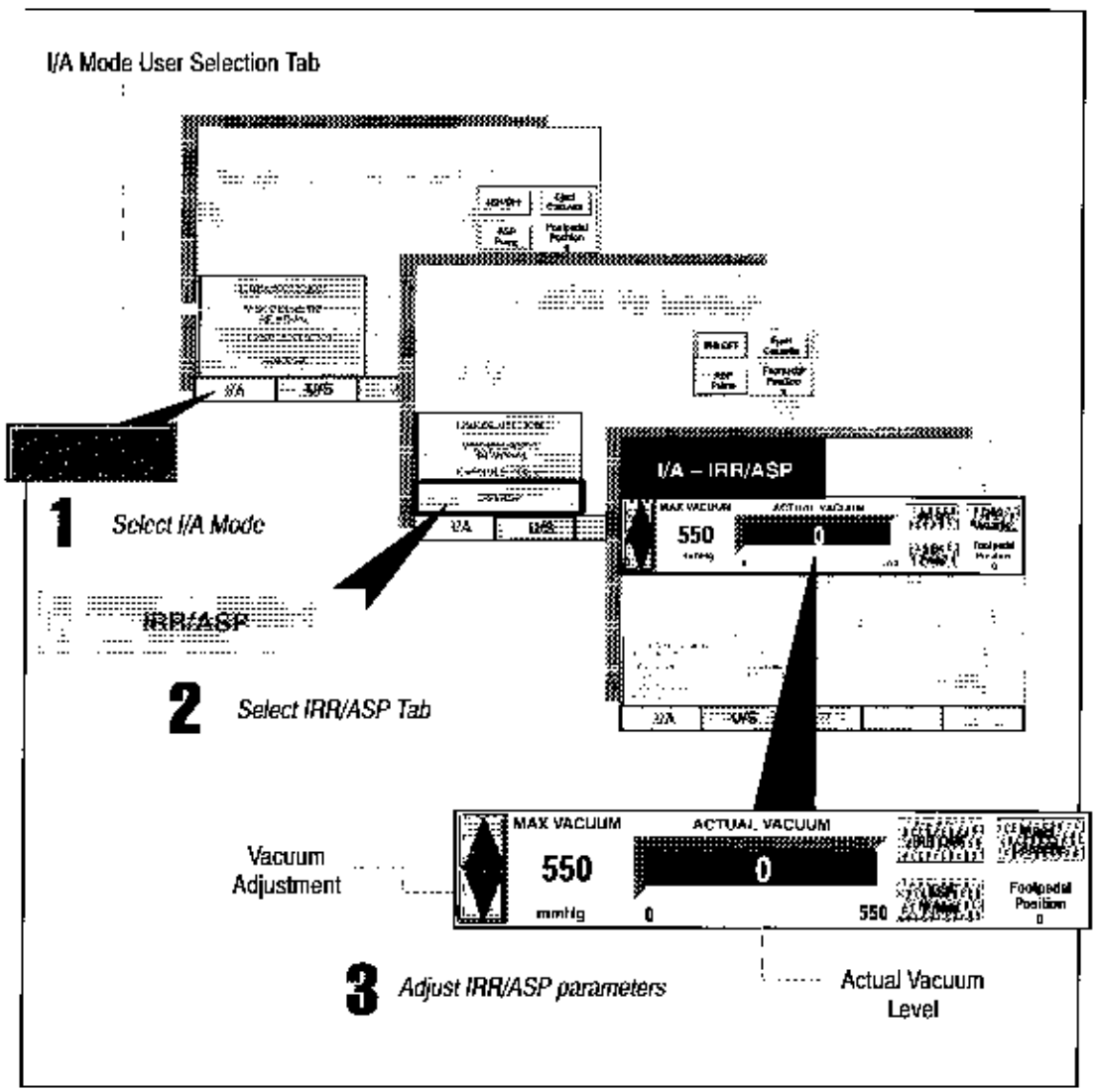


Using Your System in Surgery

Ultrasound Setup

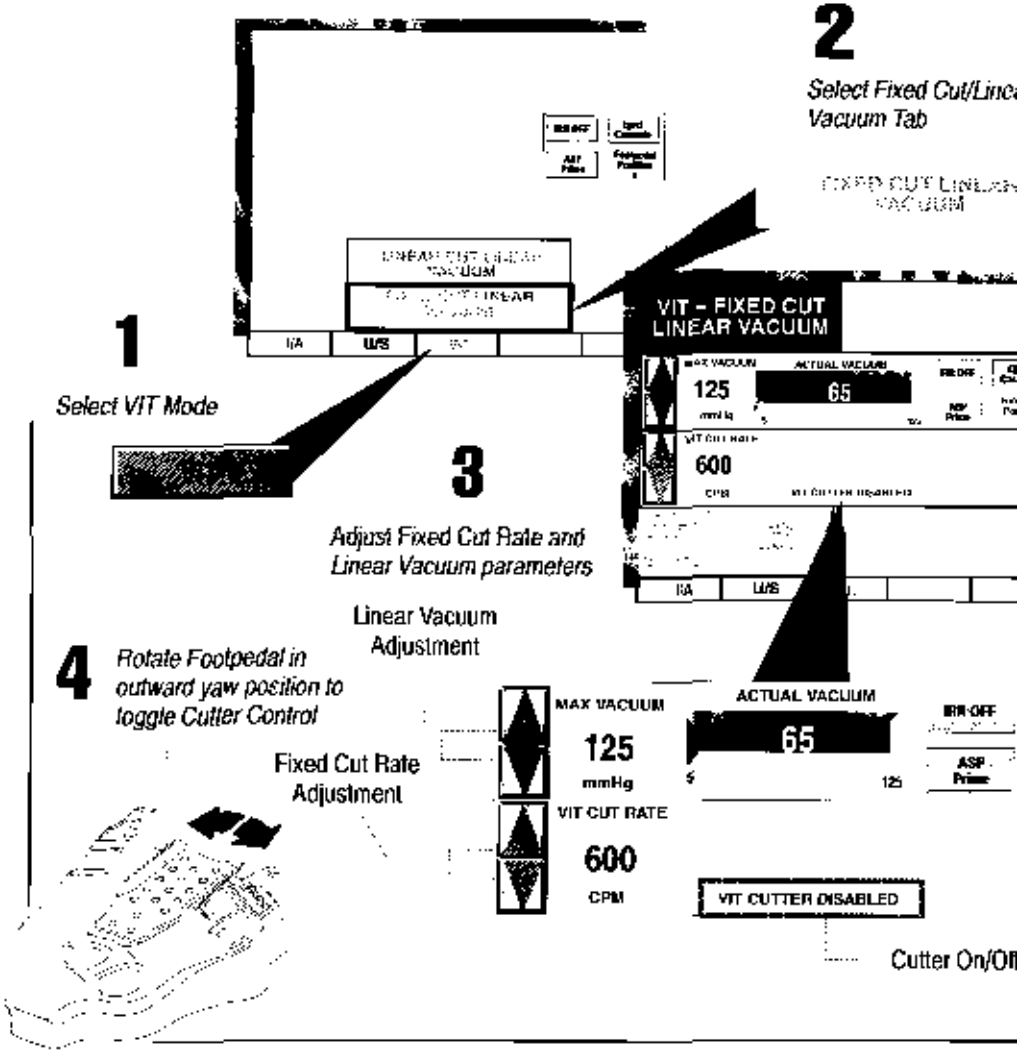


Irrigation/Aspiration Set–up

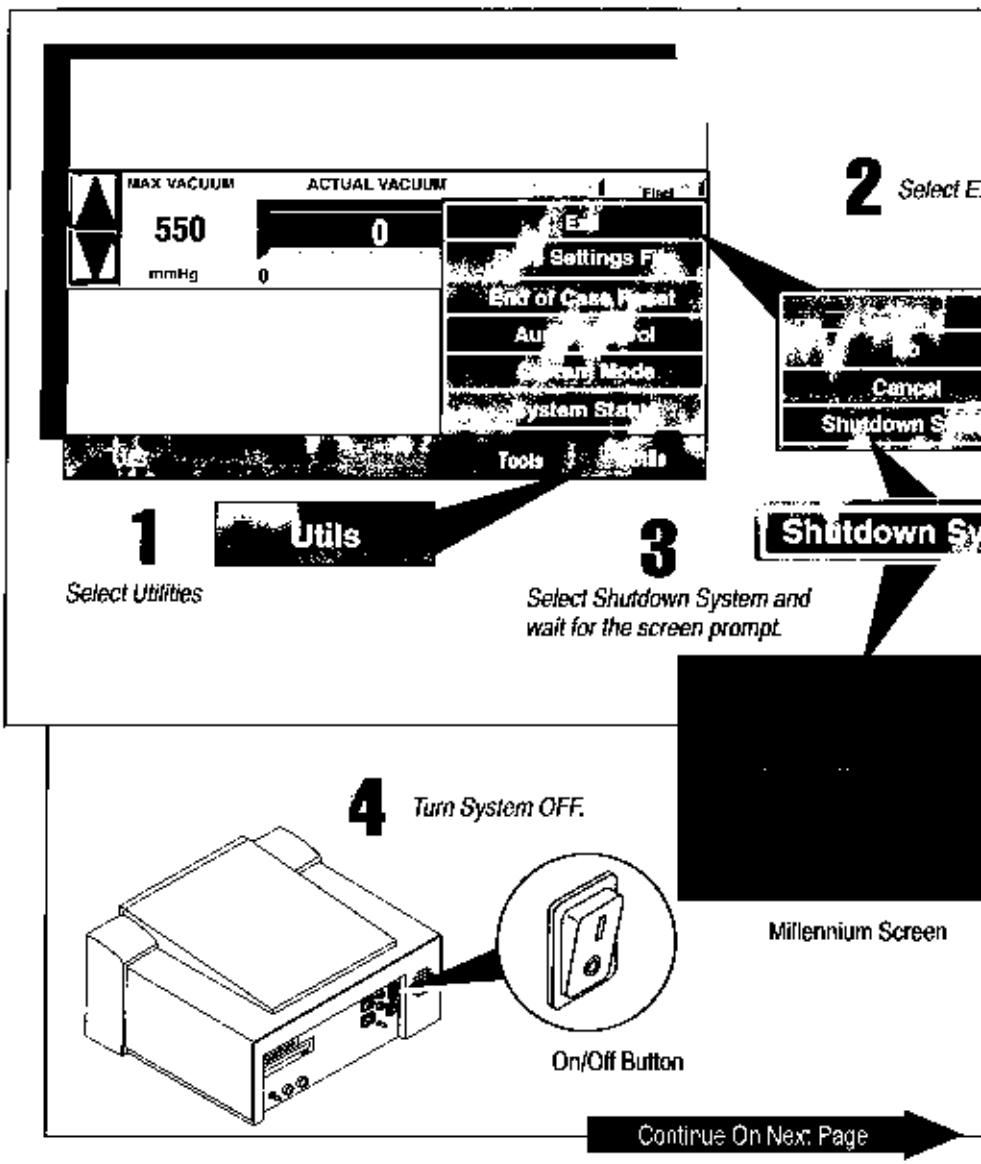


Using Your System in Surgery

Anterior Vitrectomy Set-up



Surgical Procedure Conclusion



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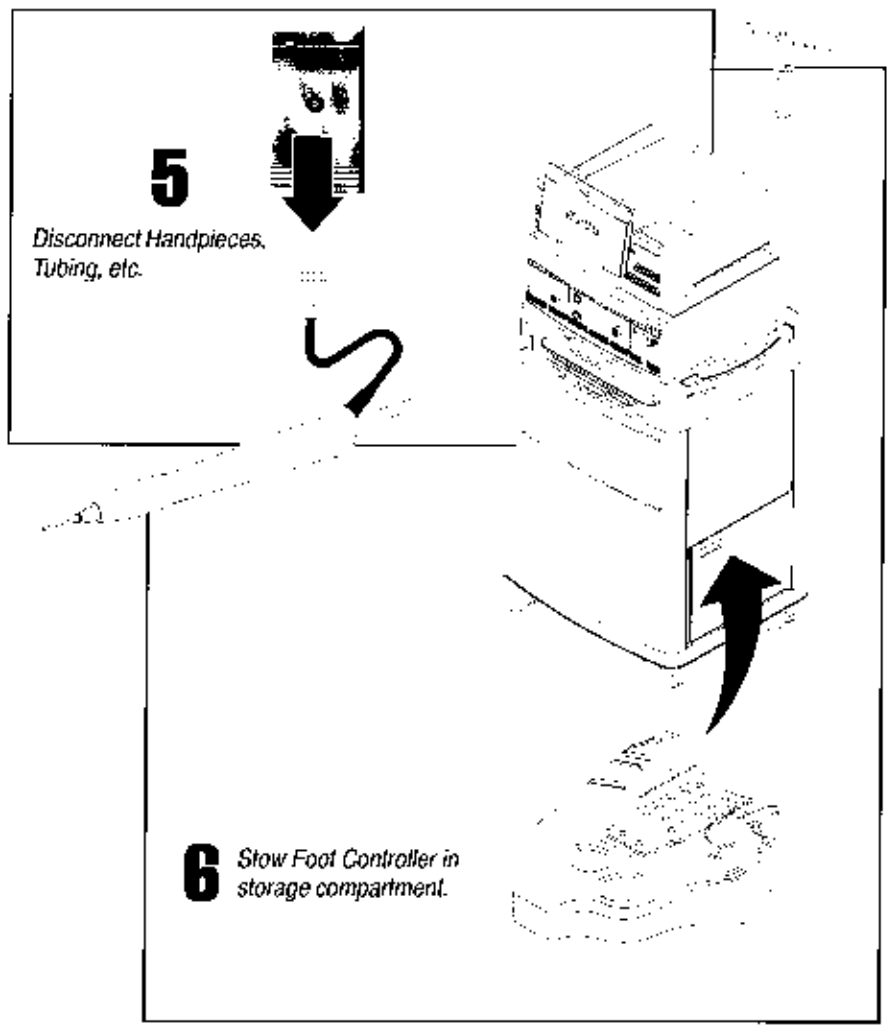
Surgical Procedure Conclusion (continued)

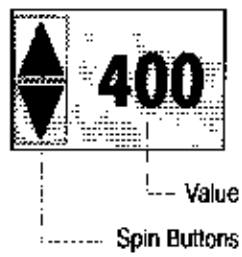


Chapter 2

User Interface

Chapter Objective: This chapter introduces you to the operating controls, displays and terminology used in this manual.

2.1. Basic Button Operations



Spin Button Control

Pressing one of these arrows will increase (up) or decrease (down) a value such as maximum aspiration. The current value is displayed adjacent to the spin buttons and under the progress bar. If a surgical tool is not in use, pressing the displayed number will take you to the numerical keypad so you can enter an exact number.

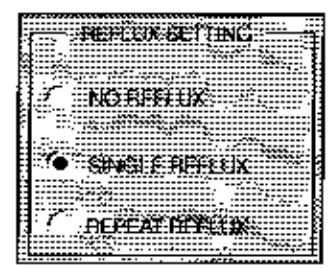
NOTE:
See page 2–2 for numerical keypad operation.

Push Button Control

This is a single button control which displays the present status, and is pressed to activate the opposite function such as insert cassette or eject cassette. It may be highlighted to indicate a selection such as "Lamp ON". No value is associated with this control and holding it down performs no additional function.

Option List Control

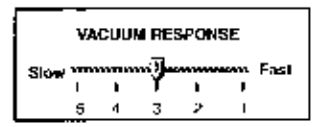
The Option List allows you to select an option. Only one option is possible at a time. Selecting one option automatically deselects others.



2.1. Basic Button Operations *(continued)*

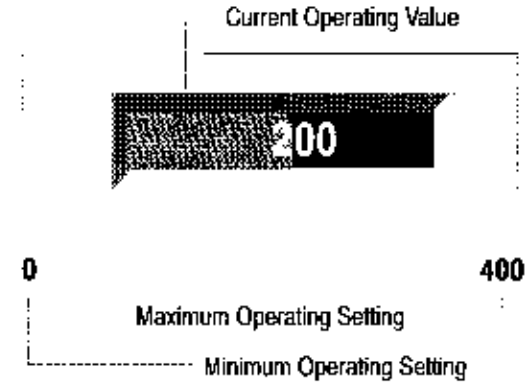
Slide Control

This type of control allows you to set the current value of an operational setting.



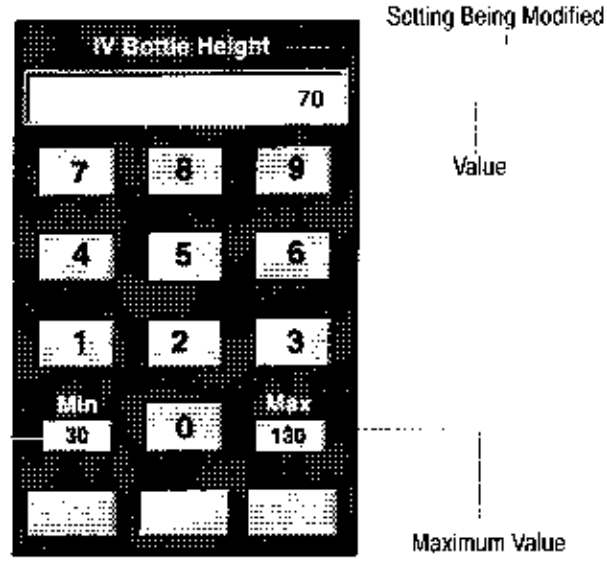
Progress Bar

A display of this type is a graphical representation of the current value of an operational setting within a specified range. It also shows the minimum and maximum settings as set by the spin buttons. Pressing the minimum operating setting numeral will open the **Numeric Keypad** for entering exact values.



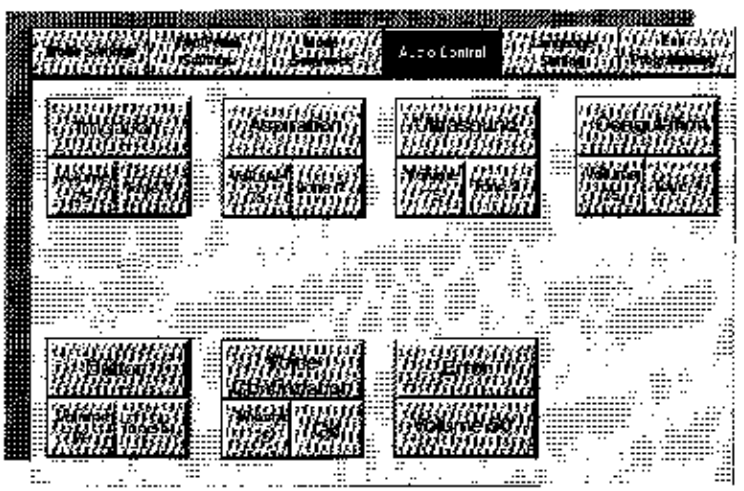
Numeric Keypad

The numeric keypad function allows you to rapidly enter numerical surgical settings or change settings without using the spin buttons continuously. Numbers are entered by touching the numeral. New values are entered from the key display as indicated.



Tab Control

These controls allow easy access to the general modes and functions of the system. Each mode is placed on a separate tab which is placed across either the top or bottom of the screen like file folders. You may visually scan across these tabs to find the appropriate mode or function, press on the tab, and a second menu will open to allow you to select a specific operating function. The screen shown below is for the Audio Control tab only. Other tab screens will appear differently.



Pop-Up Window

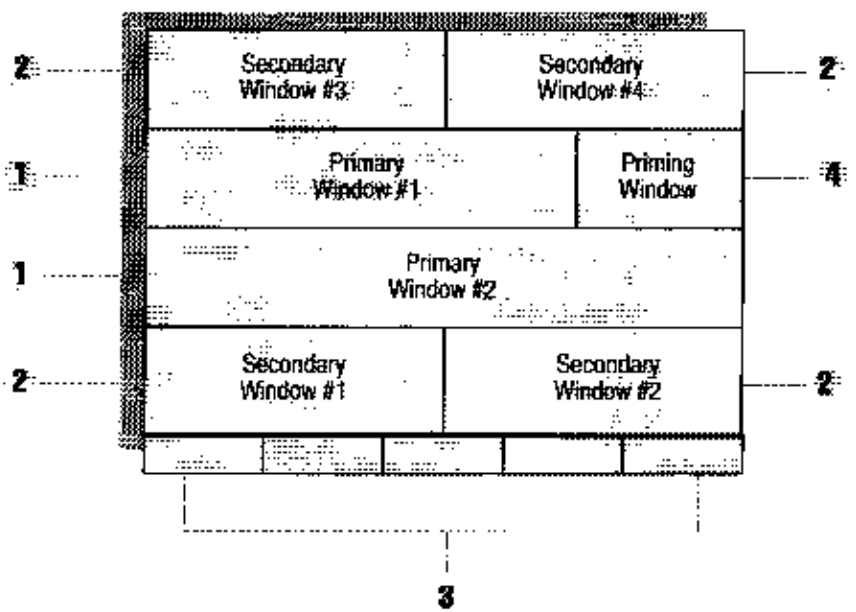
This type of window appears to display error and warning messages. You must take the appropriate action (see chapter 7). Nothing else can be done on the screen while a pop-up window is on the screen. The surgeon may be able to continue with the procedure depending upon the error.

2.2 User Interface Concepts

This section describes the general concepts of the ***Storz Millennium™ Microsurgical System*** user interface.

Screen Layout

The screen is separated into two primary windows, four secondary windows, a priming window and seven tabs.



1 **Primary Windows** (2): Used to display major operating functions such as: Aspiration, Phacoemulsification, Vitrectomy, Scissors or Coagulation. These locations are fixed. There can be no more than two of these functions active at a time.

2 **Secondary Windows (4):** Used to display secondary functions such as: Illumination or IV Pole. The first tool activated is placed in window #1 and additional tools are placed in consecutive windows (up to 4 windows). To activate a fifth tool, you will be prompted to close another before the desired tool can be activated.

3 **User Tabs:** Used to allow you to select the current operating mode, activate or deactivate functions, display on-line help, or exit the system. When a tab is pressed, it will expand upward **(see next two pages)** to display multiple choices for that selection. Only one of these selections may be activated at a time.

4 **Priming Window:** This window is always active when it is displayed.

2.2. User Interface Concepts *(continued)*

Anterior Surgical Modes

The functions activated by these tabs are explained in chapter 4.

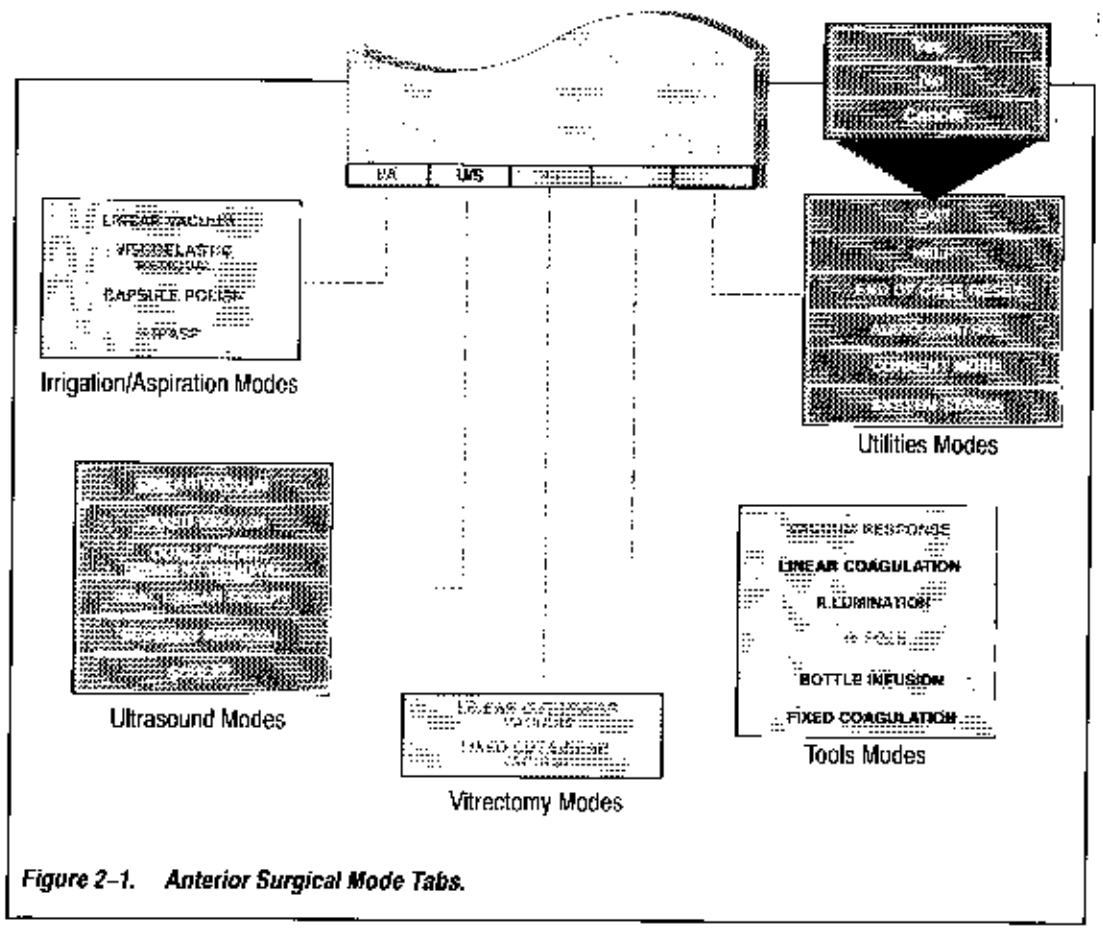


Figure 2–1. Anterior Surgical Mode Tabs.

Posterior Surgical Modes

The functions activated by these tabs are explained in chapter 4.

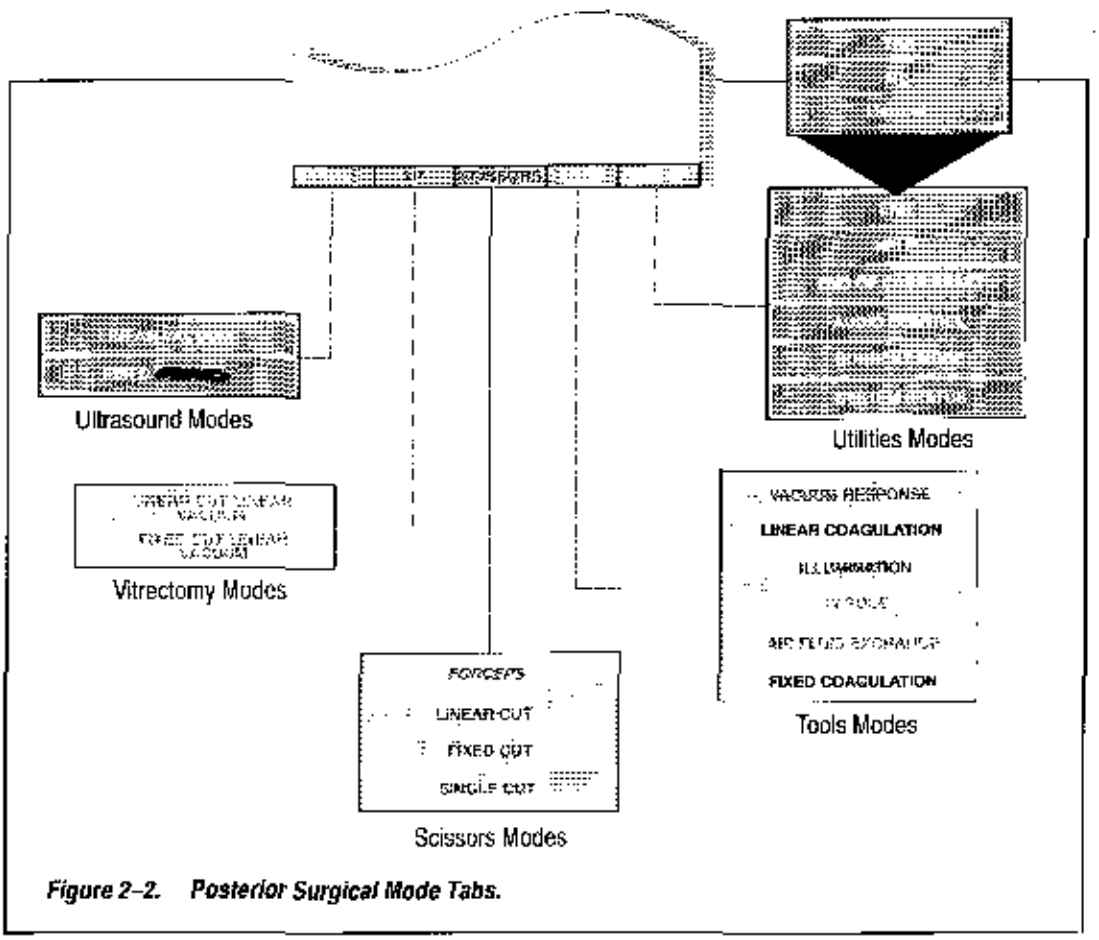
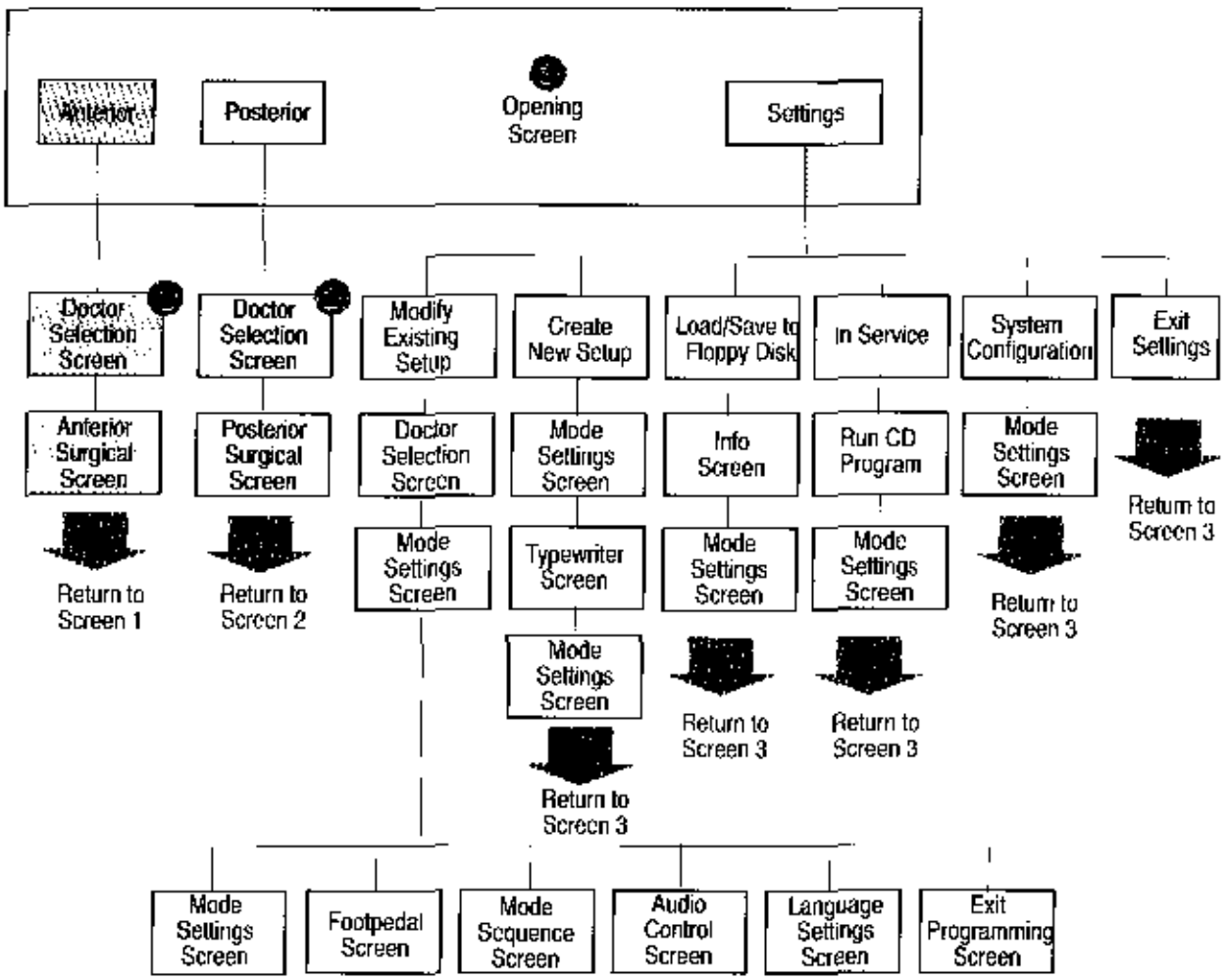


Figure 2–2. Posterior Surgical Mode Tabs.

2.3. User Interface Screens

System Hierarchy

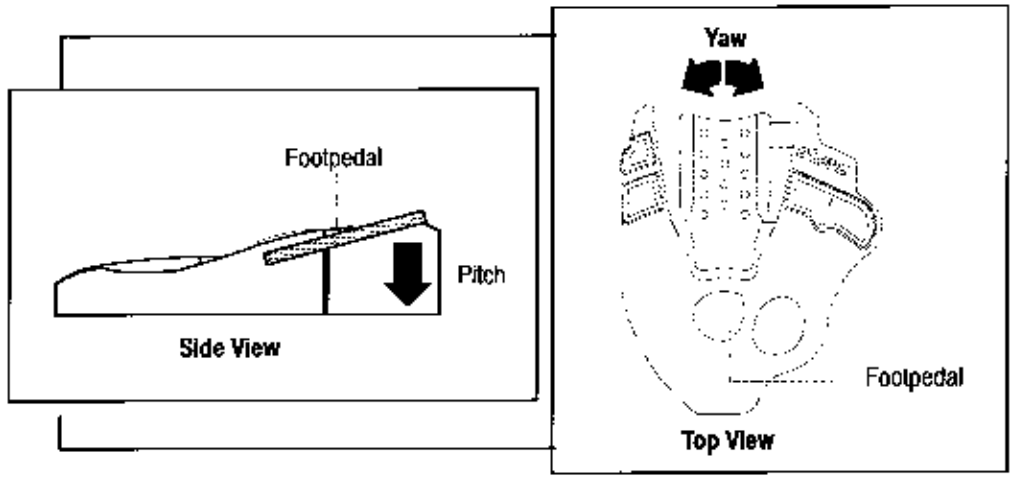
This diagram shows the sequence by which the various screens may be selected. Pressing **EXIT** takes you back one screen.



2.4. *Foot Controller*

The ***Foot Controller*** is the main interface between the surgeon and the ***Storz Millennium™ Microsurgical System.*** The surgeon can control most of the available functions from the foot controller. In some operating configurations the surgeon can also change modes from the foot controller. The foot controller is attached to the system via a twelve foot cord. It is water tight, corrosion resistant, and ergonomically shaped to minimize foot fatigue.

The ***Foot Controller*** has two axes of movement so that two functions may be controlled simultaneously. The center pedal operates with both the pitch and yaw travel. The control of linear functions is proportional to amount of foot pedal travel. In single linear mode, the pitch controls the linear functions selected. The programmable detents provide tactile feedback when entering the region programmed for each function. The yaw movement simulates the side switches used on some systems. It is used to activate such functions as vitrectomy cutter and reflux. The yaw functions are programmable for left–foot and right foot users. In dual linear mode, aspiration is always controlled by pitch travel, and the other linear functions are controlled by yaw travel.



Basic Button Operation

Refer to figure 2–3 for the following information.

The rocker switch is a programmable three position momentary switch which automatically returns to the center position when released. This switch functions like the spin–buttons on the touch screen to control operating levels or to change to the next operating mode in a preselected sequence.

The function switch is a programmable two–position (ON/OFF) switch used to control one of the functions. Press once to turn function ON, and again to turn it OFF.

The blue fixed coagulation switch is a momentary ON switch used to activate coagulation functions when selected and enabled via the screen.

NOTE:
Voice confirmation (if enabled) responds to foot controller operation but not on–screen buttons.

The System Status Screen is used to convey the current footpedal configuration to the surgical team. When a Doctor's name is selected, or the **SYSTEM STATUS** tab is pressed, this box will be displayed to show the current foot controller configuration. Programming of these controls is discussed in chapter 3. The data conveyed in this box is:

- *User File* – the name of the user file being used.
- *Footpedal Setup* – right or left foot. Reflux is programmed to inside motion of the foot.
- *Reflux* – single reflux, repeat reflux, or no reflux.
- *Dual U/S YAW U/S* – allow for extra aspiration.
- *Function Switch* – setup functions user has programmed such as: IV pole emergency up, next mode or previous mode.
- *Rocker Switch* – operating settings user has programmed such as: aspiration level, phaco power, etc.
- *Ultrasound* – indicates average power, elapsed time, and absolute power.
- *I/V Height* – Height of IV bottle.
- *Vacuum Response* – relationship of foot pedal travel to vacuum response.

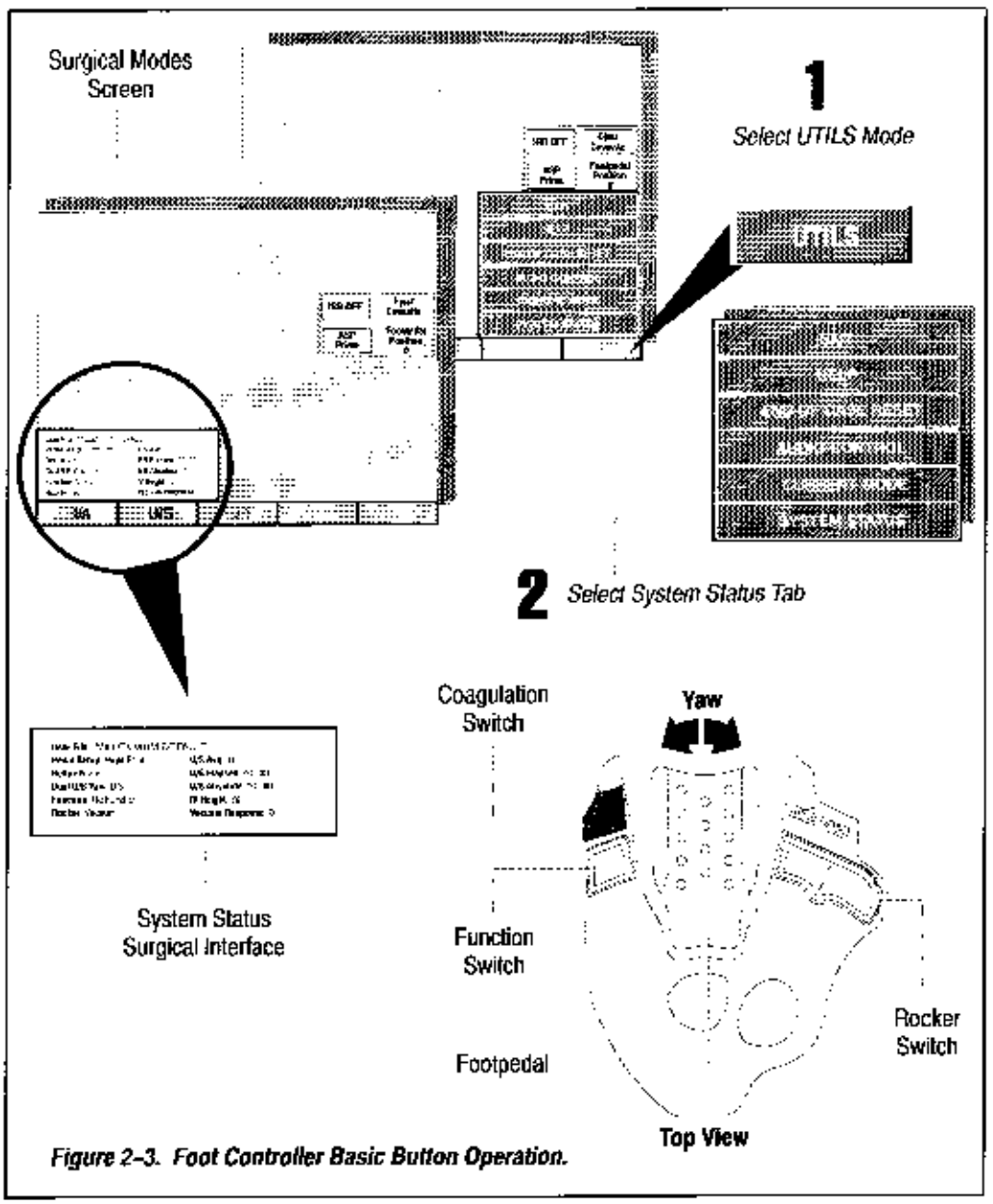
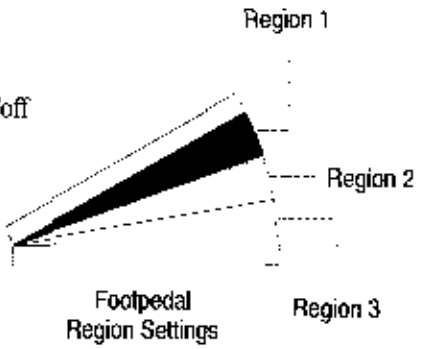


Figure 2–3. Foot Controller Basic Button Operation.

Linear Control

The center pedal provides two axes of movement and on/off controls by using pitch and yaw movements of the pedal. Each of these controls is programmable with respect to function and control parameters.

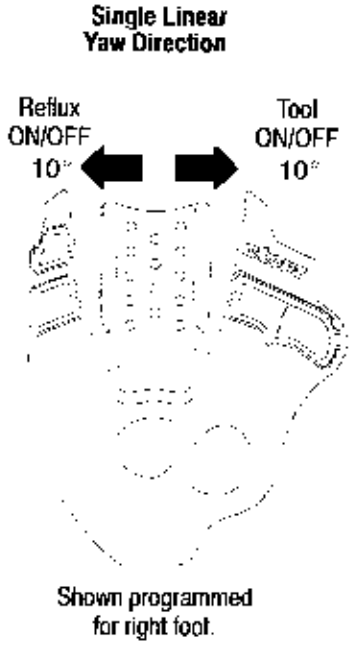


Single Linear Control Description

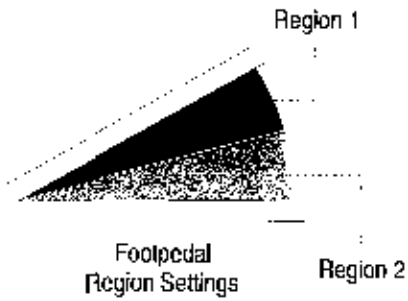
In the pitch direction, the center pedal will provide approximately 15° of up/down movement. Within this movement, there are three programmable regions (two detent positions). When the foot pedal travels from one region through a detent position to the next region, there will be a momentary increase in foot pedal resistance. When released, the foot pedal will return to the home (up) position. The pitch movement is programmed to provide linear control as a function of relative foot pedal displacement (e.g., 0° to 15° down corresponds to 0% to 100% output).

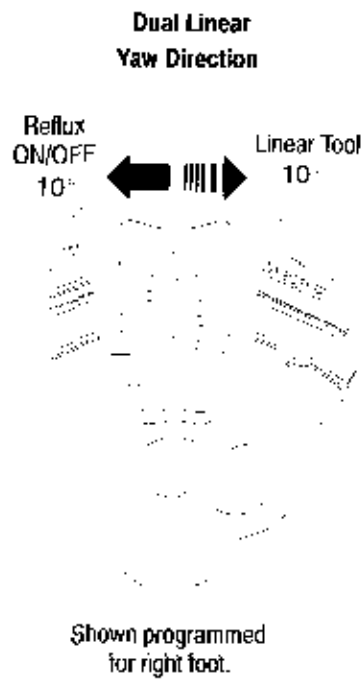
Region	[redacted]	2	3
Default Setting	[redacted]	30%	50%

In the yaw direction, the center pedal will provide approximately 10° of travel in both the left and right directions. When the footpedal is released, it returns to the center position. The outward yaw movement provides ON/OFF control, each successive outward movement toggles the programmed tool ON or OFF. Each successive inward yaw movement toggles reflux ON or OFF (see page 4-9).



The footpedal may be programmed for use with either the right or left foot. Reflux (if selected) is always activated by inward yaw displacement. As the figure shows, for a right foot configuration, reflux is to the left (inward). For a left foot configuration, reflux would be to the right.





Dual Linear Control Description

In the pitch direction, the center pedal will provide approximately 15° of up/down movement. Within this movement, there are two programmable regions (one detent position). When the foot pedal travels from one region through a detent position to the next region, there will be a momentary increase in foot pedal resistance. When released, the foot pedal will return to the home (up) position. The pitch movement is programmed to provide linear control as a function of relative foot pedal displacement (e.g., 0° to 15° down corresponds to 0% to 100% output).

Region	
Default Setting	

In the yaw direction, the center pedal will provide approximately 10° of travel in both the left and right directions. When the footpedal is released, it returns to the center position. The outward yaw movement provides linear control of the programmed tool as a function of relative footpedal displacement (e.g., 0° to 10° corresponds to 0% to 100% output). There is no output of linear yaw displacement until there is pitch displacement. Each successive inward yaw movement toggles reflux (if selected) ON or OFF (see page 4–9).

The footpedal may be programmed for use with either the right or left foot. Reflux (if selected) is always activated by inward yaw displacement. As the figure shows, for a right foot configuration, reflux is to the left (inward). For a left foot configuration, reflux would be to the right.

Chapter 3

Customizing Your System

Chapter Objective: This chapter explains how to customize your ***Storz Millennium™ Microsurgical System*** to achieve maximum flexibility for your operating needs.

3.1. Mode Programming

NOTE:
Surgical devices may not be operated during programming.

Each surgeon using the ***Storz Millennium™ Microsurgical System*** can program the system for their own preferred operating configuration and instrument parameters. This is accomplished by entering the mode programming screens from the **SETTINGS** pushbutton on the main screen. From the settings screen, you may choose tabs to modify an existing setup, create a new setup, or transfer setup data between floppy disk and hard drive.

Create a New Setup (see figure 3-1)

NOTE:
All modules may be programmed even if they are not installed.

From the **Settings** screen, press the **Create New Setup** tab. You must then choose to create an anterior or posterior setup file by pressing the corresponding button. The system default settings are initially displayed when entering this screen. When new settings are made, they are saved under a new user name. You may now change the settings to your preferences as explained in **Modifying an Existing Setup** (page 3-3) and **Saving Your Personal Settings** (para. 3.2 on page 3-12).

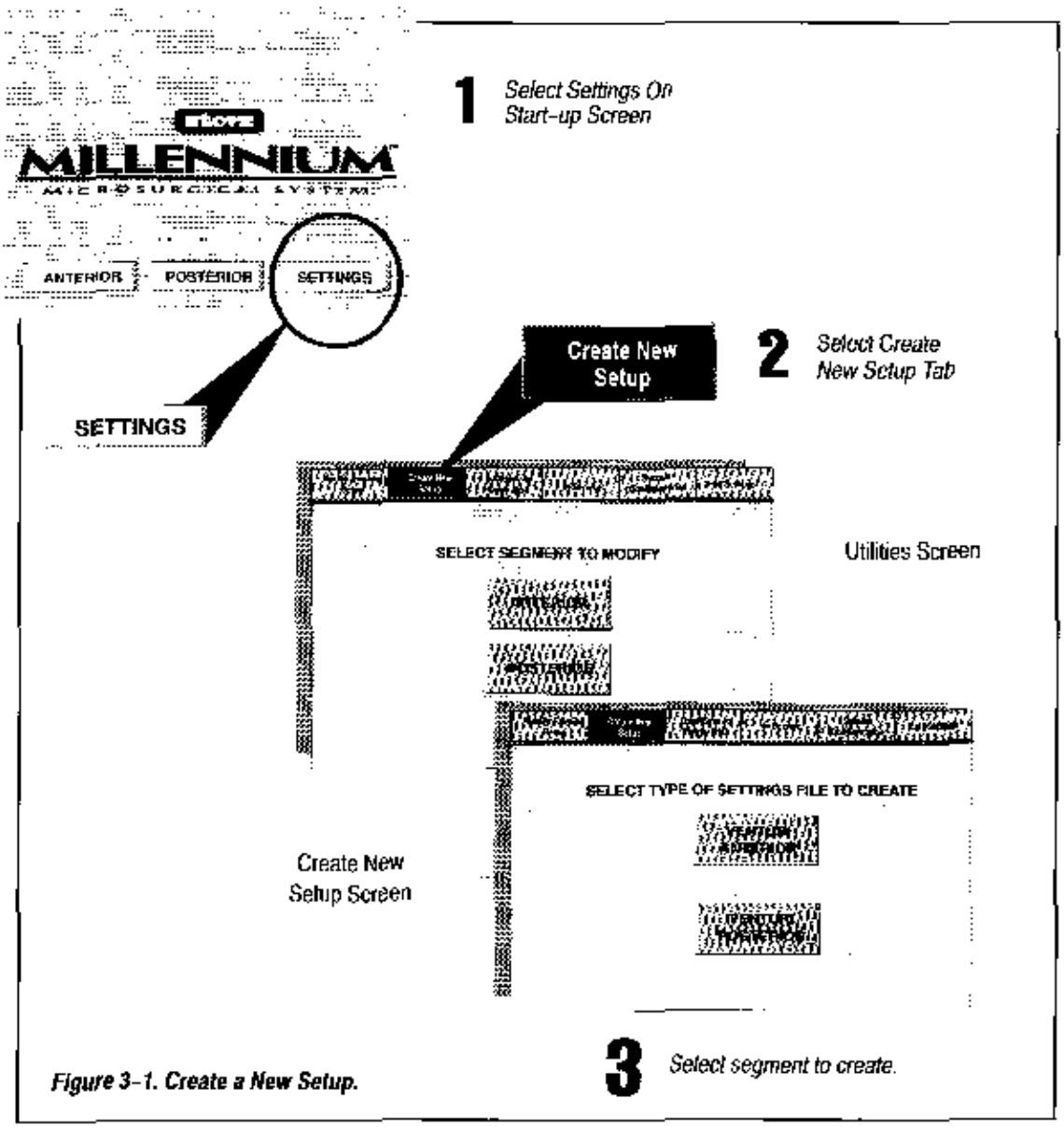


Figure 3–1. Create a New Setup.

Modify an Existing Setup *(see figure 3–2)*

From the **Settings** screen, press the **Modify Existing Setup** tab. Choose **ANTERIOR** or **POSTERIOR.** A window will be displayed from which you must choose the doctor setting to modify. Press **YES** to continue to the **Setup** screens. The following figures show each of the setup screens in which you may make modifications to the parameters.

NOTE:
Default settings cannot be modified.

- **Mode Settings**– *Set the operating parameters for each operating mode (see figure 3–3 on page 3–5).*
- **Footpedal Settings**–*Select the footpedal settings (see figure 3–4 on page 3–6).*
- **Mode Sequence**–*You may program the selection sequence of modes by selecting a single push button depression, change tab sequence or eliminate unused selections (see figure 3–5 on page 3–7).*
- **Audio Control**–*Set the audio tones and volume for surgical functions and the error tone. Set voice confirmation volume or turn it off (see figure 3–6 on page 3–8).*
- **Language Setting**–*Select the language to be used (see figure 3–7 on page 3–11).*

When all the desired settings are made, press the **Exit Programming** tab and the exit screen is displayed. This screen allows you to save the changes or ignore all the changes. When you choose to save the changes, the **Save** window will be displayed, and you will be prompted to enter a surgeon's name as explained in paragraph 3.2, on page 3–12.

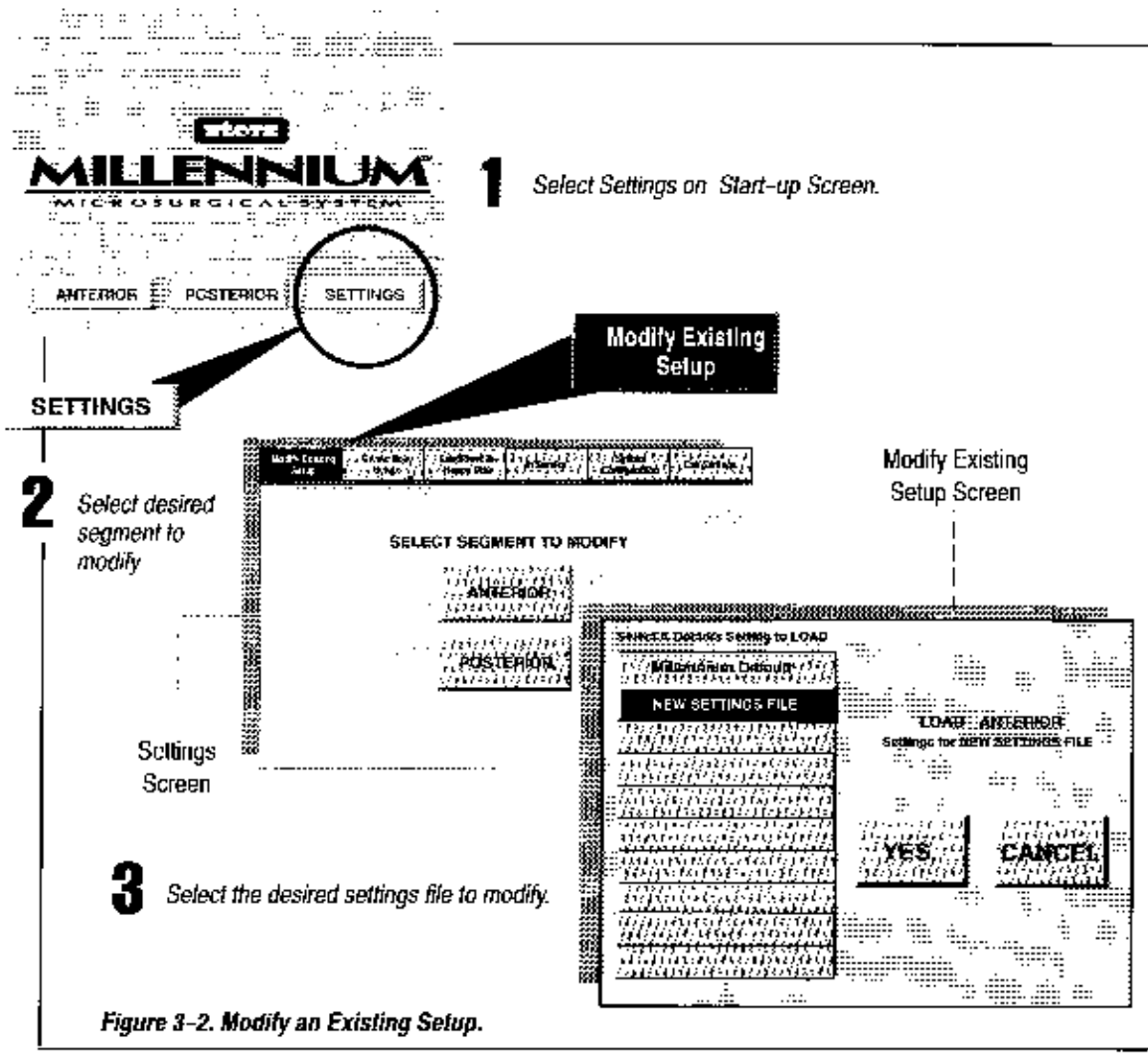


Figure 3-2. Modify an Existing Setup.

Customizing Mode Settings

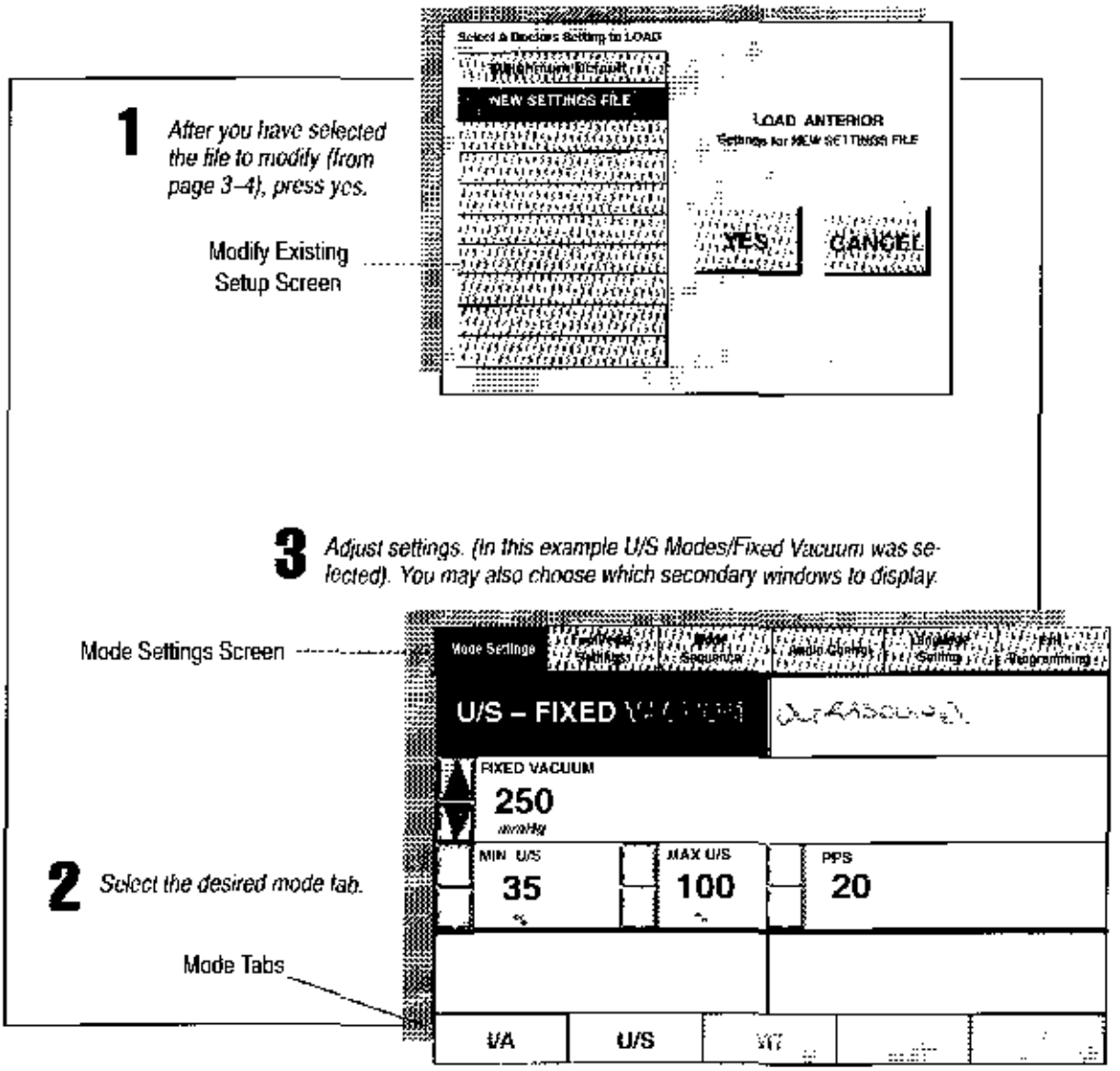


Figure 3–3. Customizing Mode Settings

Customizing Footpedal Settings

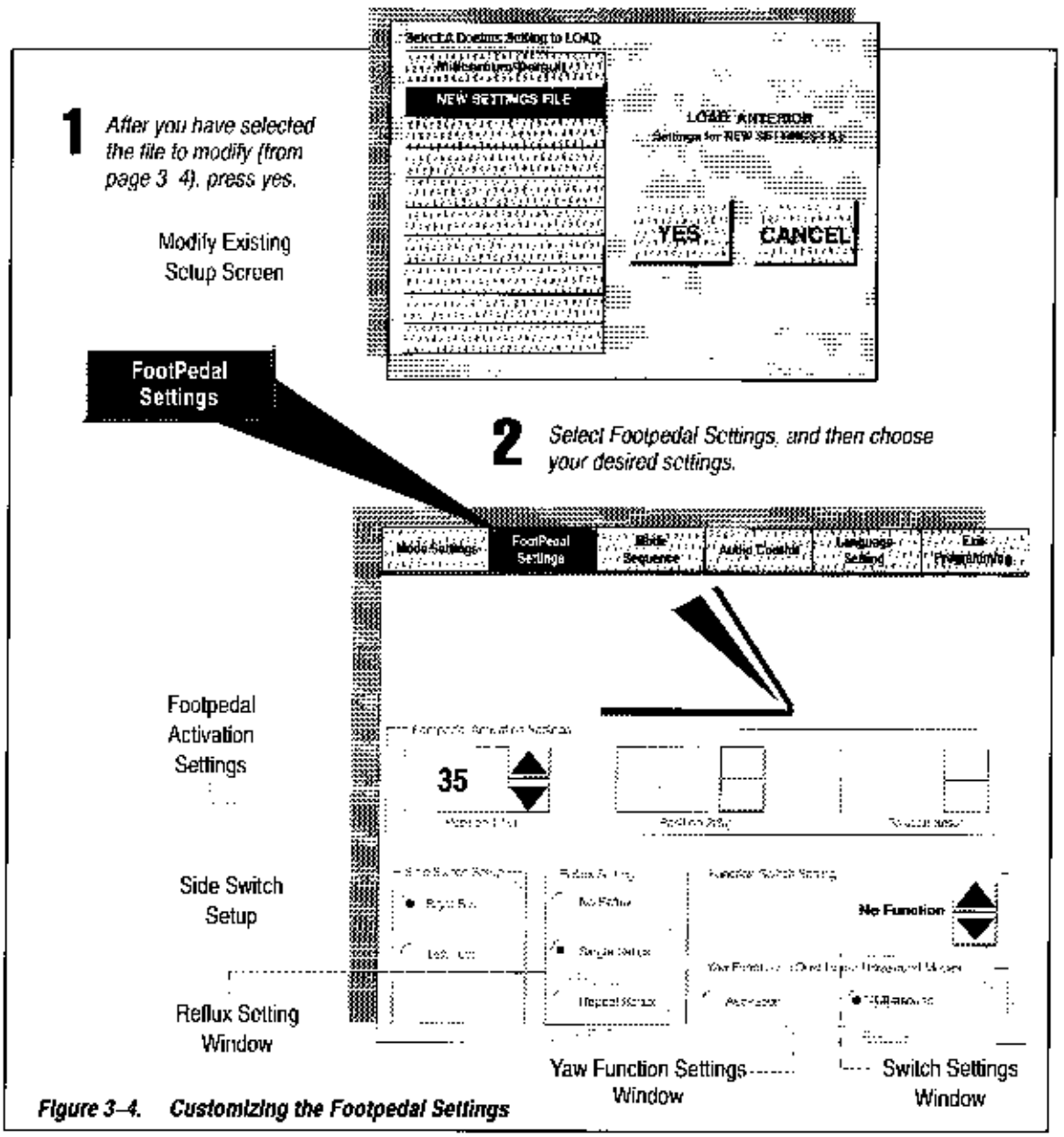


Figure 3–4. Customizing the Footpedal Settings

Customizing the Mode Sequence

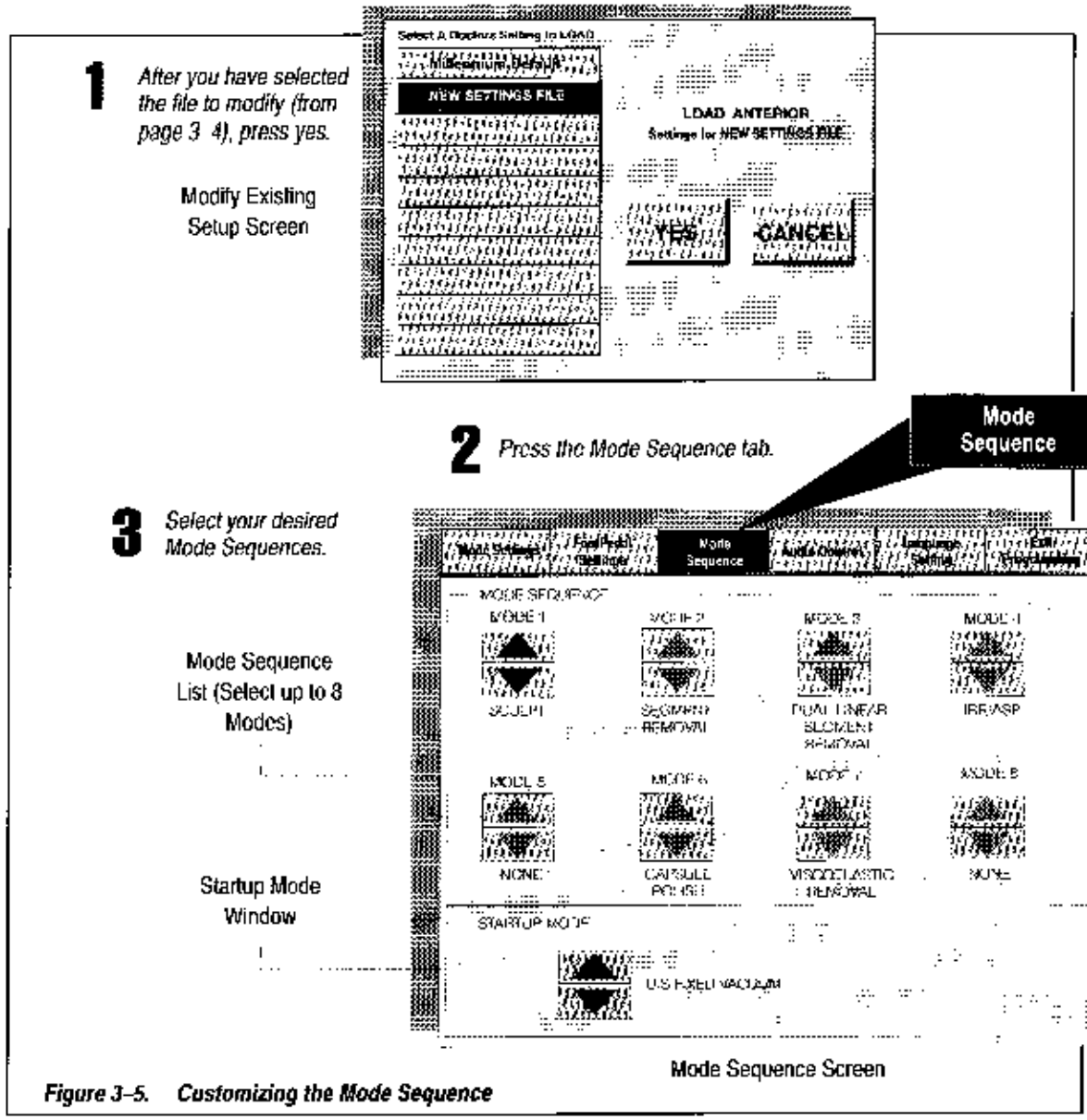
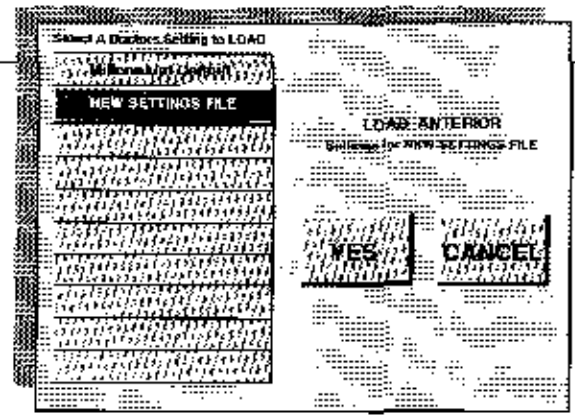


Figure 3–5. Customizing the Mode Sequence

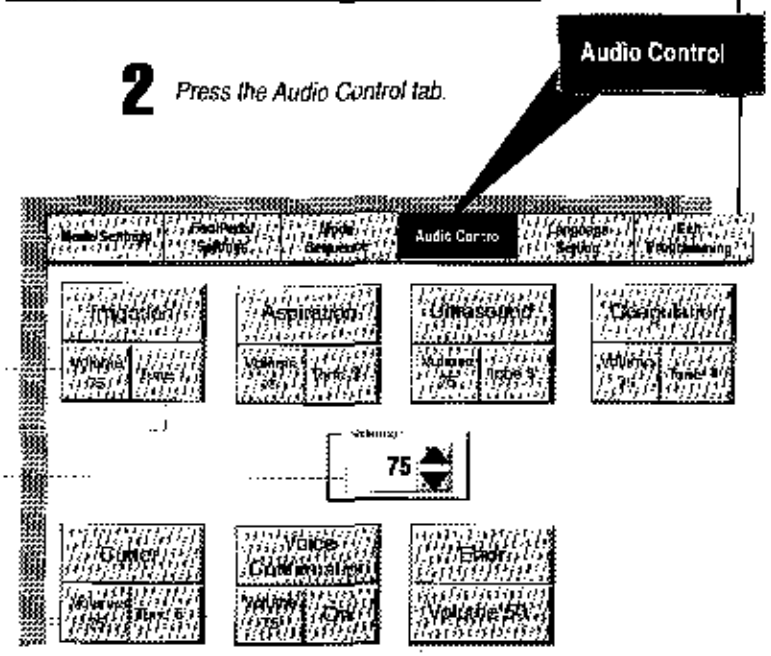
Customizing Audio Control



1 *After you have selected the file to modify (from page 3 4), press yes.*

Modify Existing Setup Screen

2 *Press the Audio Control tab.*



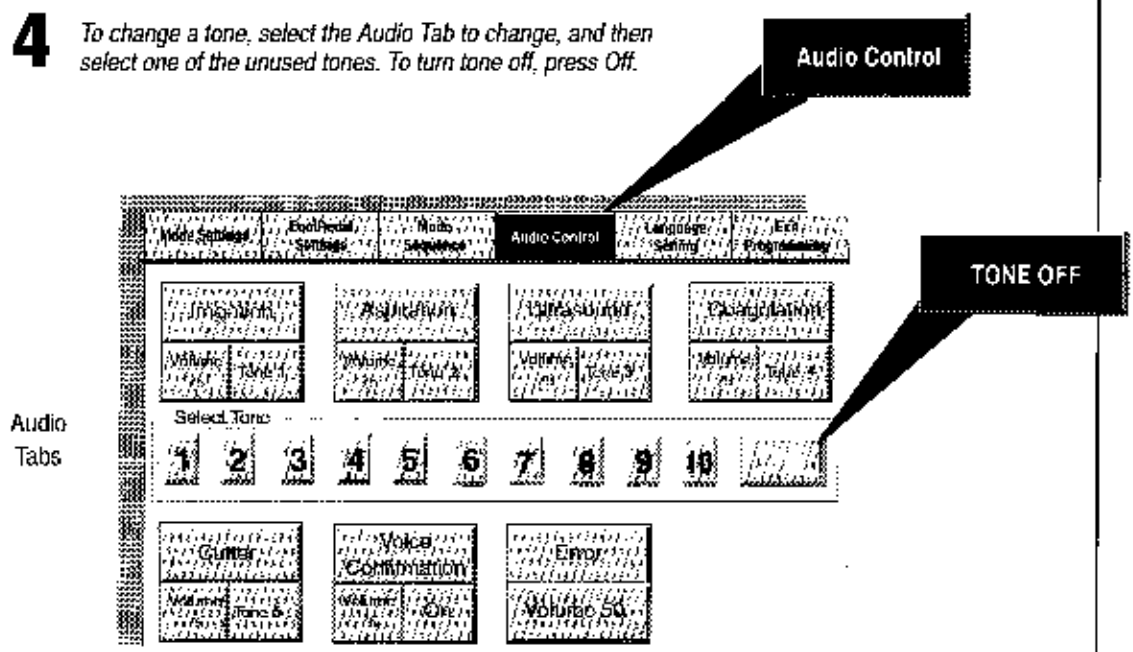
3 *Adjust the volume for each tone as desired. The volume control for Coagulation is restricted.*

Audio Control Screen

Figure 3-6. Customizing the Audio Control

Continue On Next Page

4 *To change a tone, select the Audio Tab to change, and then select one of the unused tones. To turn tone off, press Off.*



Audio Control Screen

5 *Select one of the Audio Tabs that was turned off, and then select a new tone for it.*

Continue On Next Page

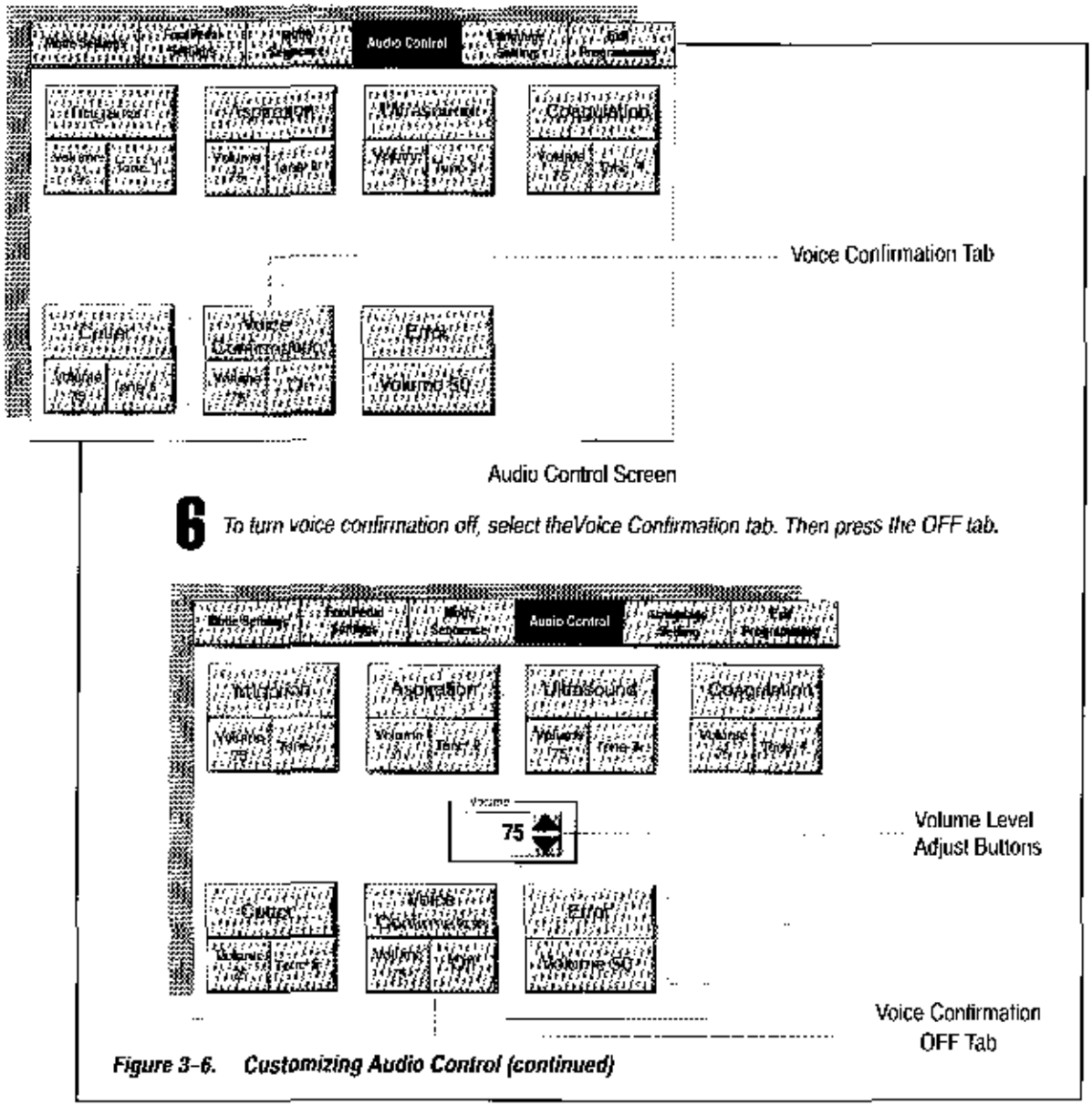


Figure 3–6. Customizing Audio Control (continued)

Customizing Language Setting

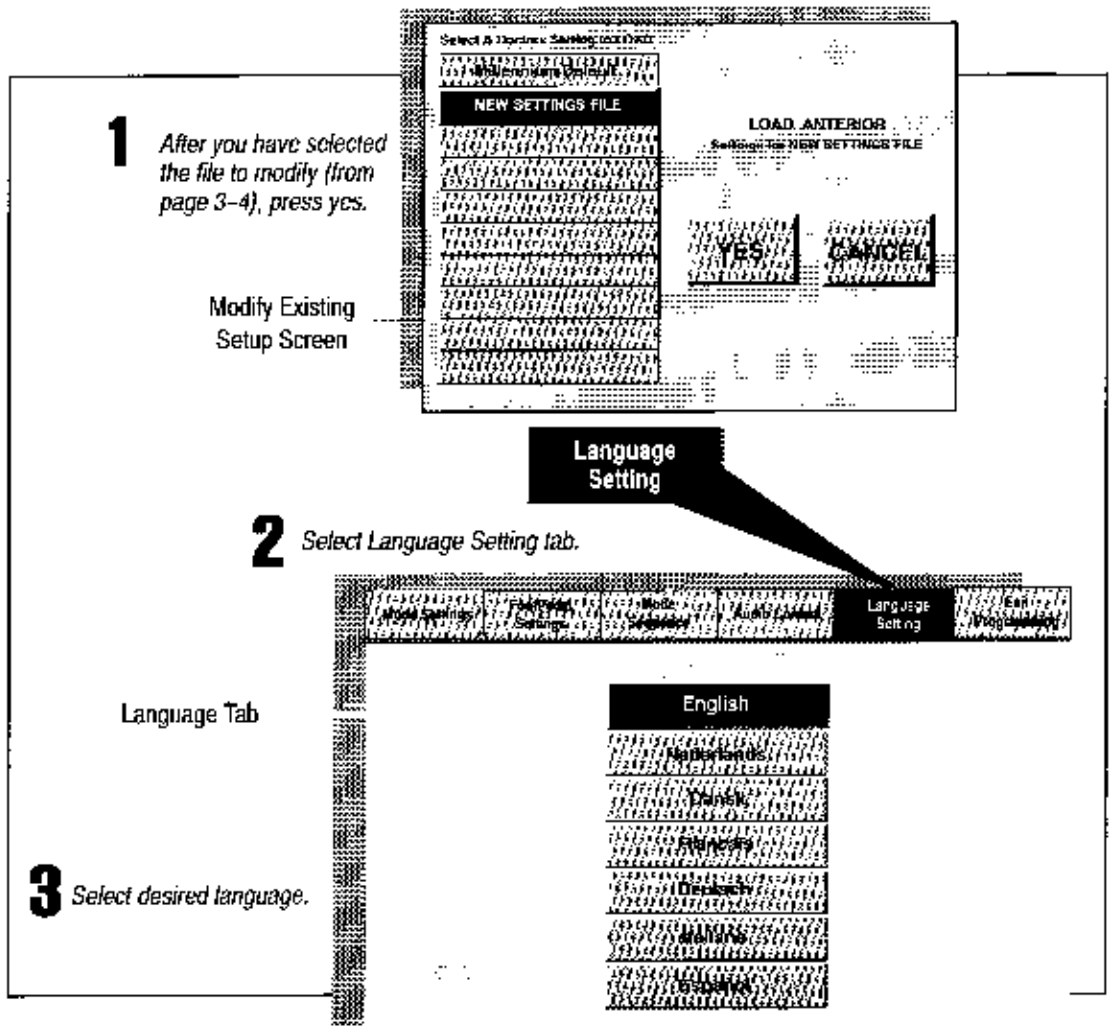


Figure 3–7 Customizing Language Setting

3.2. Saving Your Personal Settings

When you have completed entering the setup data, press **Exit Programming**. A confirmation window will open asking if you want to permanently save these settings. If you do, a window will open displaying the typewriter interface screen. The typewriter function interface allows you to enter the file name to the setup file. Characters are entered by pressing the appropriate keys. Press **EXIT** when finished. You will return to the settings window *(page 3-4)*.

NOTE:
You may rename from 1 to 4 U/S Modes.

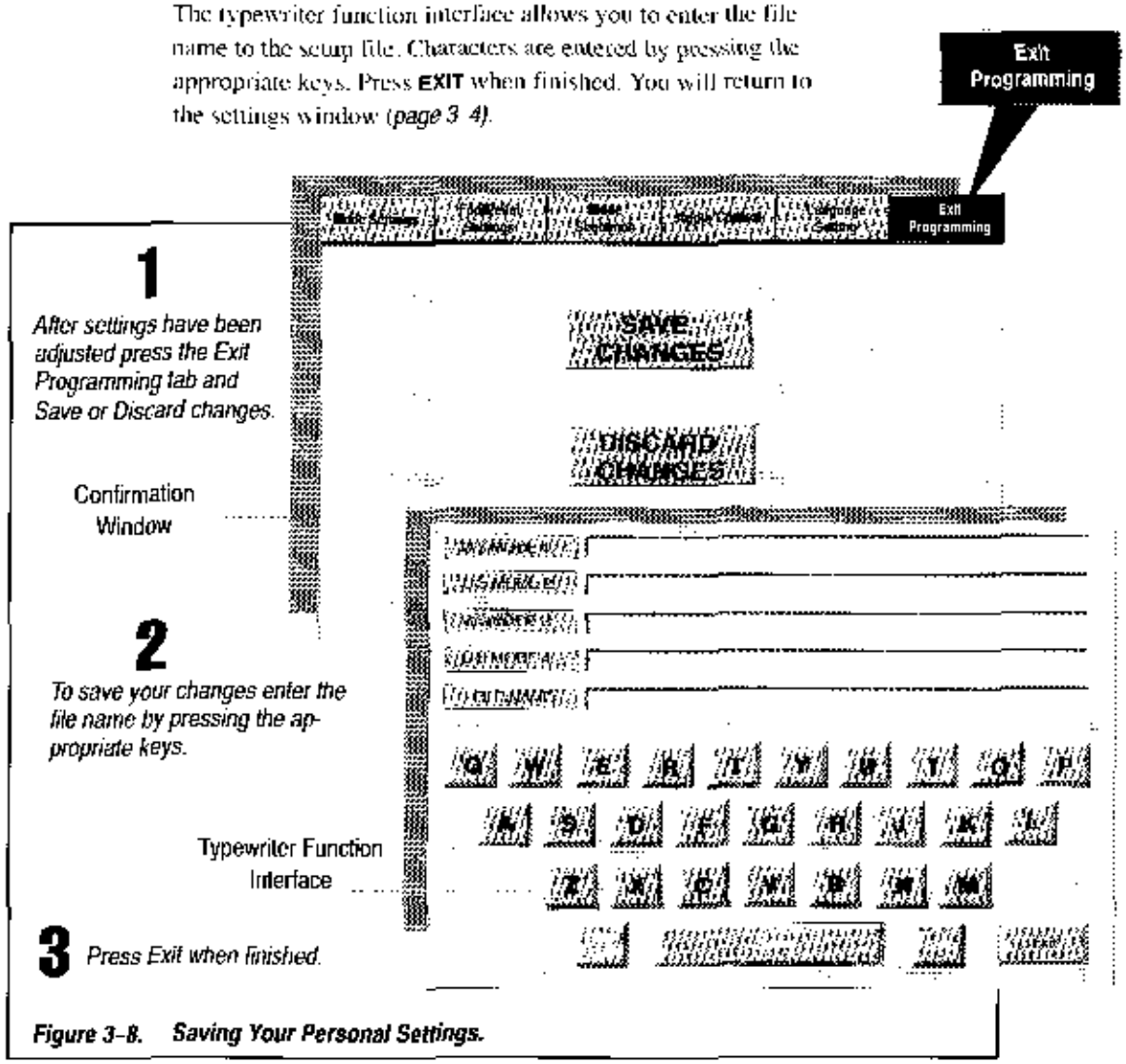

Exit Programming
Exit Programming
1
After settings have been adjusted press the Exit Programming tab and Save or Discard changes.
SAVE CHANGES
DISCARD CHANGES
Confirmation Window
2
To save your changes enter the file name by pressing the appropriate keys.
Typewriter Function Interface
3 Press Exit when finished.

Figure 3-8. Saving Your Personal Settings.

3.3. Transferring Personal Settings from One System to Another.

Place the proper disk in the floppy drive. From the **Main** screen, press **SETTINGS**. From the **Settings** window press the **load/save to floppy disk** tab. A window will be displayed in which you must choose an action you wish to take (save, load, or delete an anterior or posterior file). The **Modify Existing Setup** screen will be displayed. Select the File Name to save, and press **YES**. When **YES** is pressed, the operation is performed automatically. Pressing **Cancel** will return you to the previous screen without performing the operation.

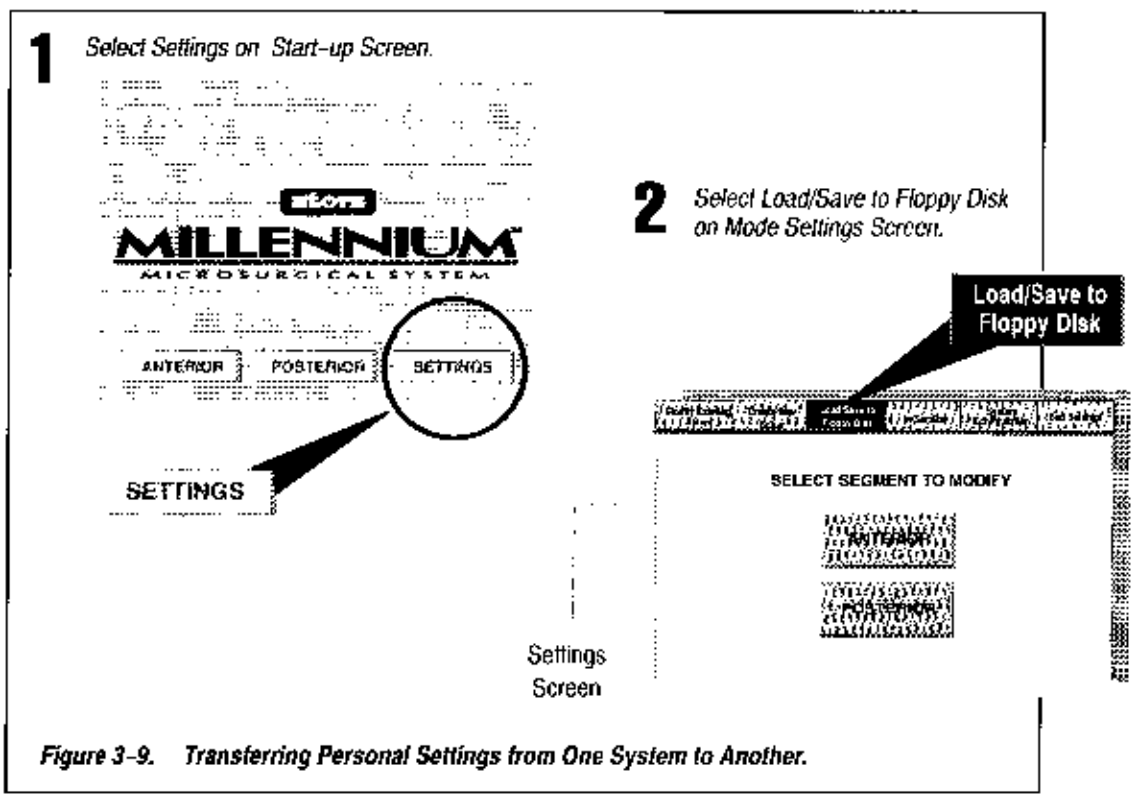


Figure 3-9. Transferring Personal Settings from One System to Another.

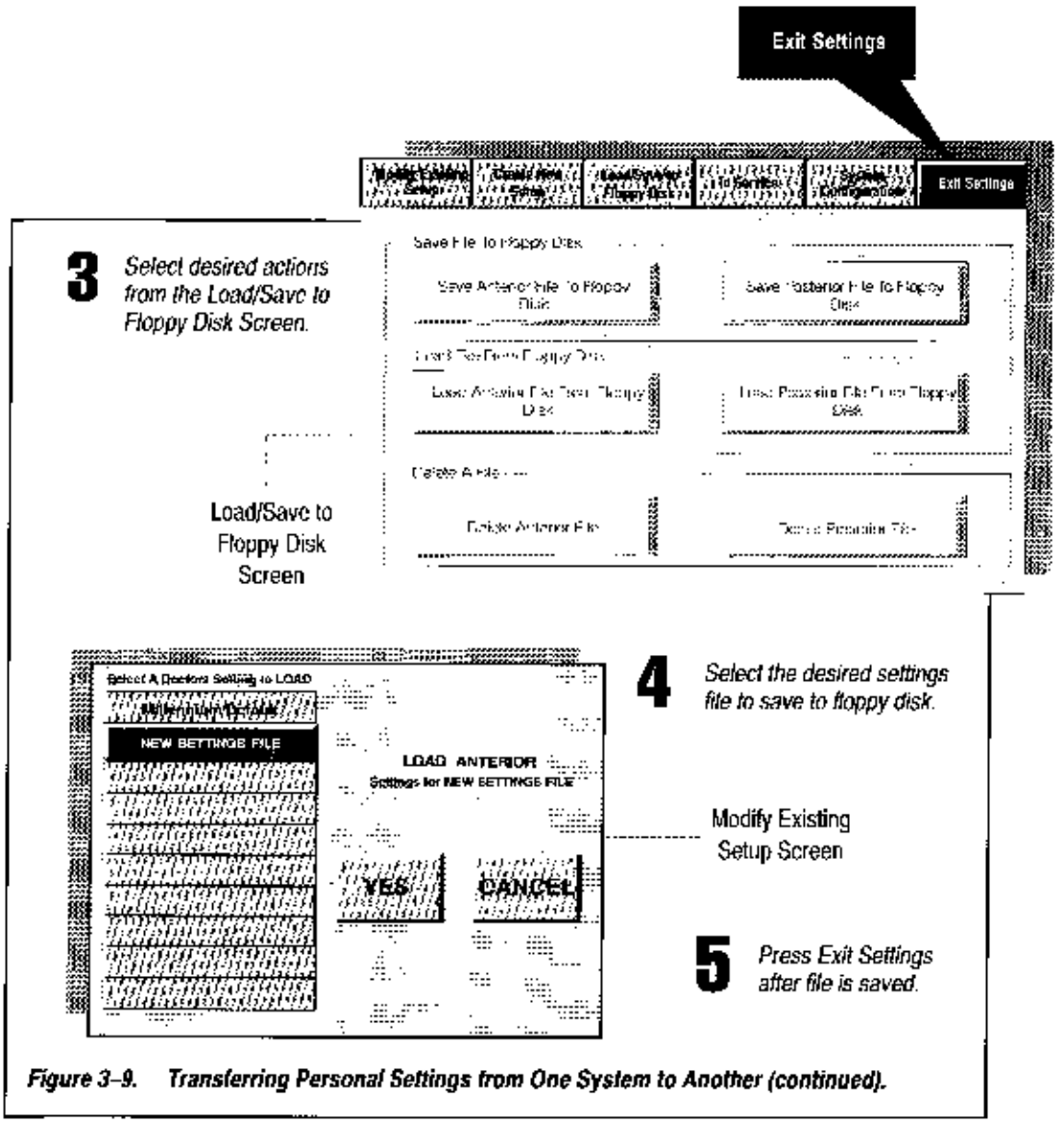
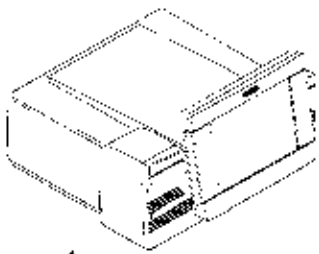


Figure 3–9. Transferring Personal Settings from One System to Another (continued).

Chapter 4

Advanced Operation

Chapter Objective: This chapter provides a detailed reference for each module and accessory, and surgical procedure setup and operation.



4.1. Computer Unit

Your ***Storz Millennium™ Microsurgical System*** is a modular design that is upgradable to take advantage of future technology evolution. The computer unit contains audio and video boards, a 1.44 MB, 3 1/2" floppy drive, a hard drive, a multimedia kit, and other electronic components. The display console includes a color display, an analog touchscreen, and an infrared remote receiver.

Located at the rear of the ***Storz Millennium™ Microsurgical System*** is the main AC power input and ON/OFF switch.

DANGER: EXPLOSION HAZARD. Do not use in the presence of flammable anesthetics, disinfectants, aerosol sprays, or in an oxygen rich atmosphere.

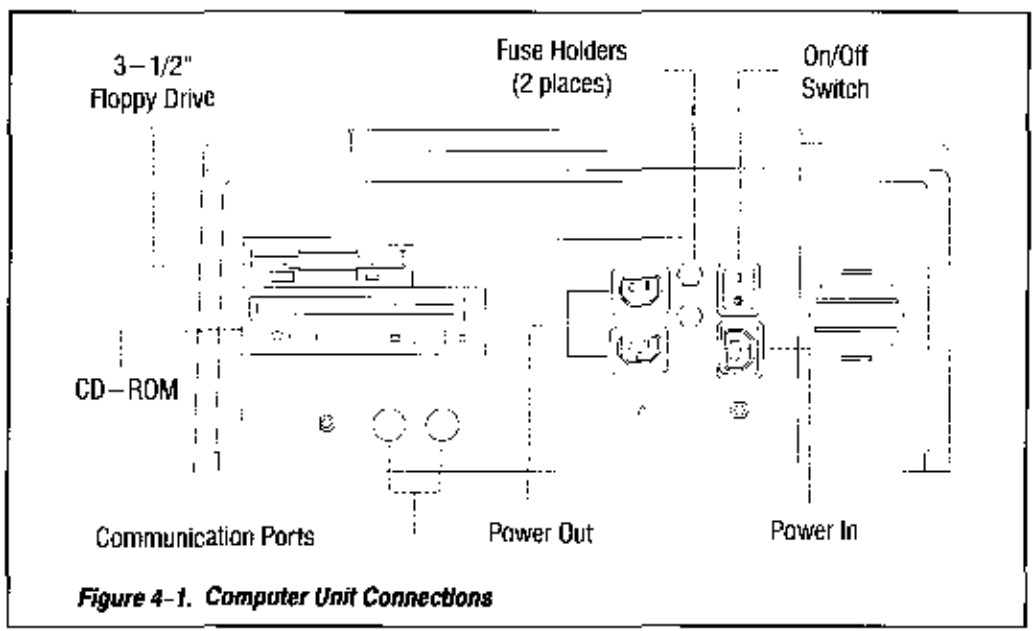
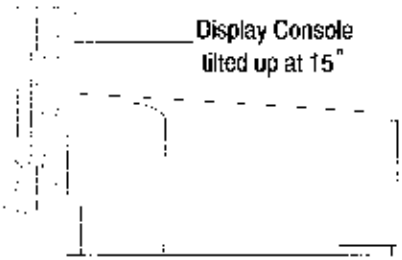


Figure 4–1. Computer Unit Connections

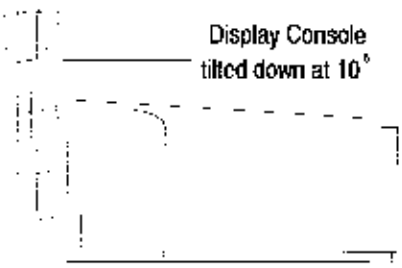
The floppy and CD drives allow you to upgrade your system without the need for a field service technician. Additionally, the floppy allows you to save, load and transfer your customized settings between systems.

Your ***Storz Millennium™ Microsurgical System*** is equipped with full multimedia capabilities to provide audio and video features. The audio portion of the multimedia kit provides warning messages, alarms, and other audio indications. The audio is generated by the sound board and two speakers located in the computer unit. The volume is adjustable via the touch screen spin–buttons on the utility screen. The video portion of the multi–media kit consists of a CD–ROM drive which can provide full visual and display capabilities. This will allow you to view animated in service manuals, operational demonstrations, etc.

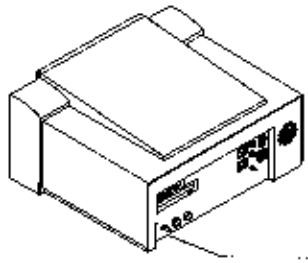
CAUTION:
Never place an irrigation bottle or any other containers of liquid on the computer unit.



The display console is the primary interface between you and your system It consists of a liquid crystal display, a touchscreen, and an infrared receiver which interfaces with the remote control. The display console may be tilted up 15° and down 10°, while the entire computer unit will swivel 45°in either direction.

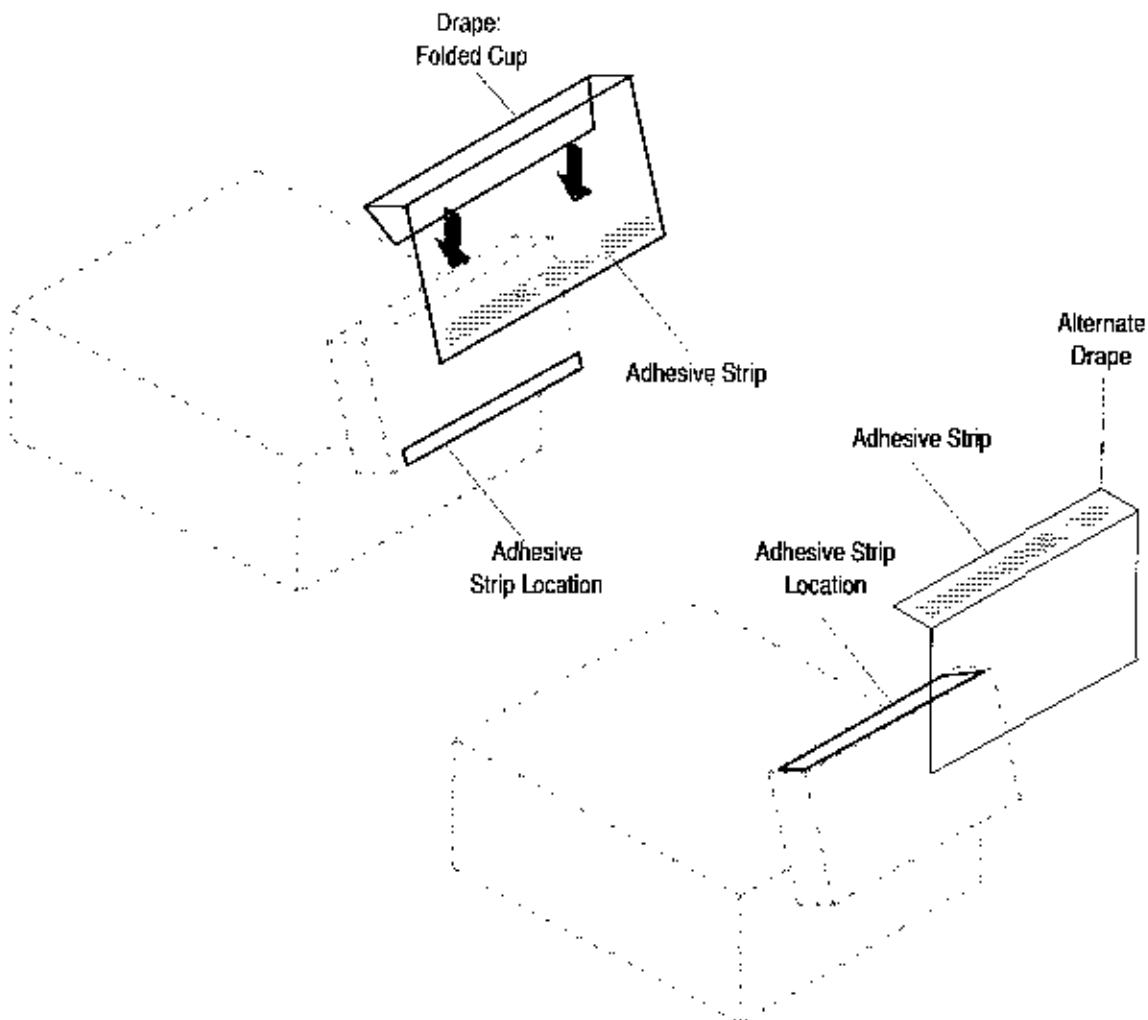


The display brightness is adjusted automatically to room light when the system is turned on. It can be overridden via a knob on the back of the computer. Once adjusted manually, the auto feature will not operate until the next time power is turned on.



Screen Drape Installation

Attach the sterile disposable drape by placing the drape over the top of the ***Storz Millennium ™ Microsurgical System*** screen and secure with the adhesive strip to the adhesive strip location as shown in the illustration below.



4.2. Base Unit.

The *Storz Millennium™ Microsurgical System's Base Unit* houses ophthalmic surgery modules. It contains a power supply module, up to five ophthalmic modules, and interconnecting circuitry for these modules. The base unit distributes power and control signals to the ophthalmic modules. Connections between the base unit and the rest of the system are located at the rear. The power supply module must always be placed in the left–most slot as shown below. It contains an interlock switch which will interrupt power to the ophthalmic modules when the front bezel of the base unit is removed. The IAV Venturi module must always be placed in the right–most slot as shown.

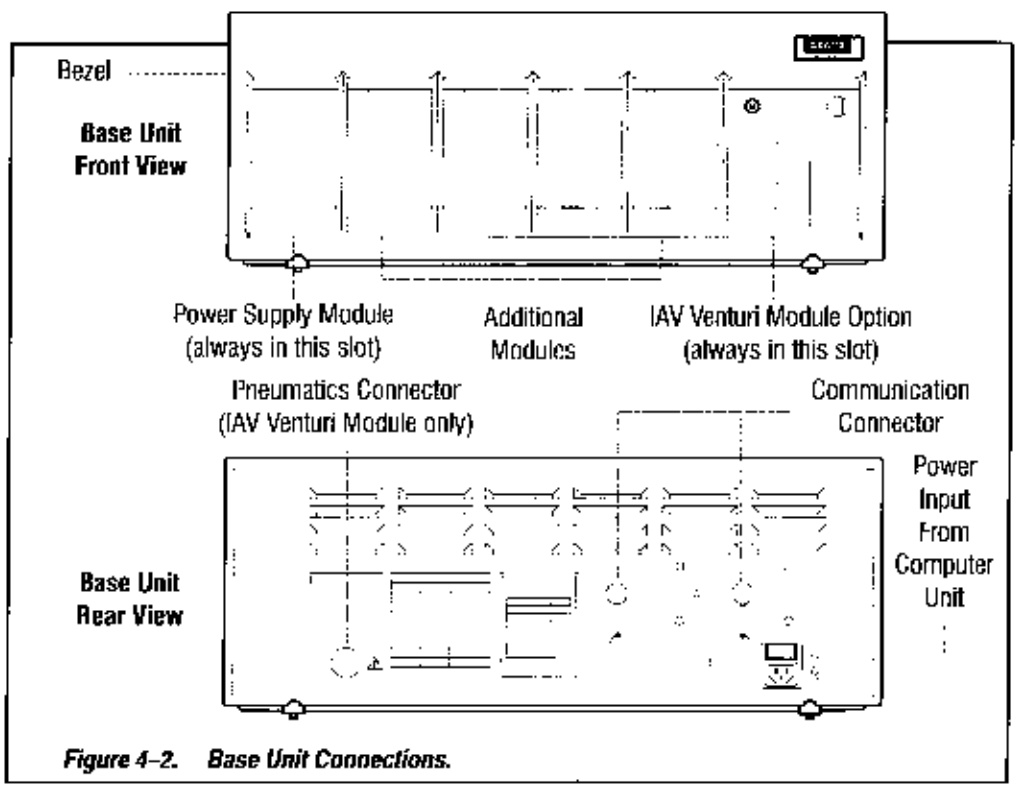
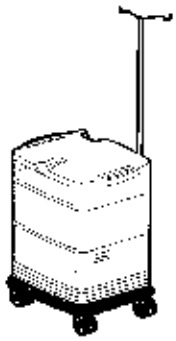


Figure 4–2. Base Unit Connections.



4.3. *Instrumentation Cart.*

The optional instrumentation cart is designed to transport and store the entire ***Storz Millennium™ Microsurgical System.*** It includes a Mayo tray, a compartment for storing the foot controller, a second compartment for storing disposable packs, an integrated IV pole, and the facilities for housing a second base unit. The cart sits on four rotating casters (the front two are locking), and it has two built–in handles (do not use the IV pole for a handle). The base unit and computer unit sit on top of the cart.

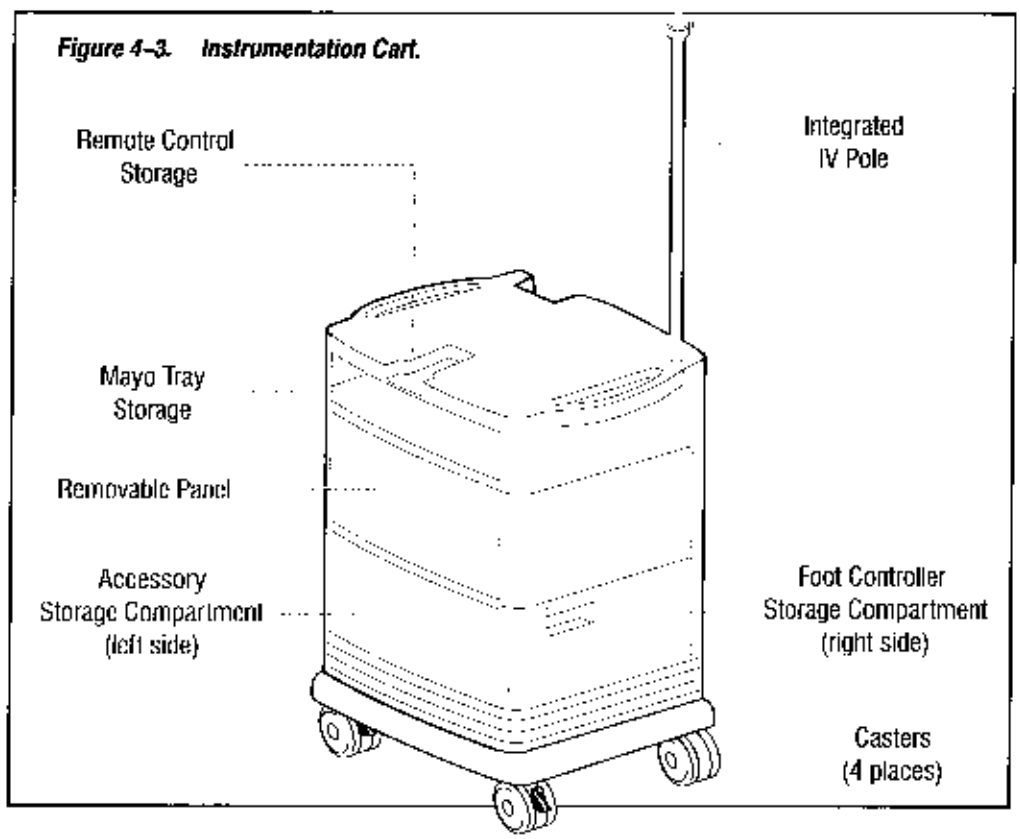


Figure 4–3. Instrumentation Cart.

4.4. IV Pole

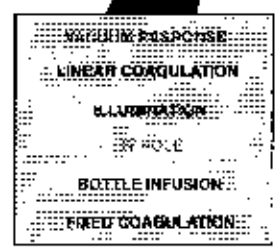
NOTE: See chapter 3 for mode programming.

The ***Storz Millennium™ Microsurgical System*** automated IV Pole is an integral part of the cart. It can be electrically controlled from the touch screen, foot controller, or remote control, or it can be pre- programmed to an ophthalmic mode. The automatic IV pole parameters can be pre- set in the utilities menu. It can travel up or down at a rate of 6 cm./sec. (2.5 in./sec.), with a positioning resolution of 1 cm. (.4 in.) and a pre-set position repeatability within 2 cm. (.8 in.).

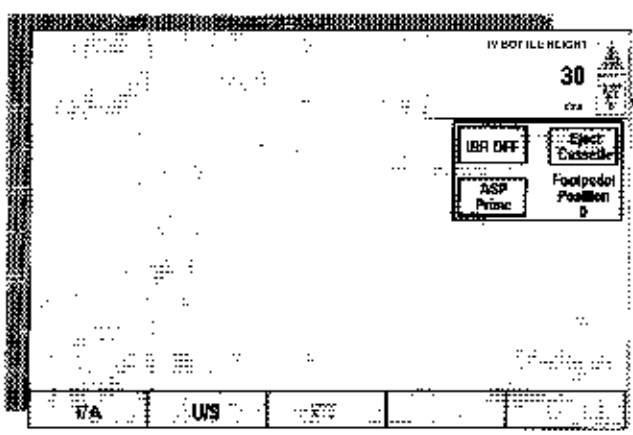
In the lowest (stowed) position, the IV pole will provide approximately 30.5 cm. (12 in.) of head pressure.

To adjust settings or to change the bottle height, press the **TOOLS** tab on the surgical mode screen, then press the **IV POLE** tab. The IV Pole spin buttons will appear in a secondary window. You may use these spin buttons to select a travel distance from 0 to 100 cm. (39.4 in.) in 1 cm. (.4 in.) increments. The zero setting is the factory offset position (approximately the patient's eye level). The IV bottle height may also be programmed (in the mode programming menu) to automatically go to a preset height when entering a particular surgical mode.

Surgical Modes Screen



IV Pole Tab



IV Pole Screen

IV Pole Adjustment

NOTE: The IV Pole adjustments may be made off screen with the remote control.

4.5. *Remote Control*

CAUTION:
The Remote Control is ***not*** *waterproof.*

The remote control transmits an infrared signal to the com puter unit which then activates the related touch screen com mand. The commands which may be given from the remote control, and their button locations are shown in the figure below.

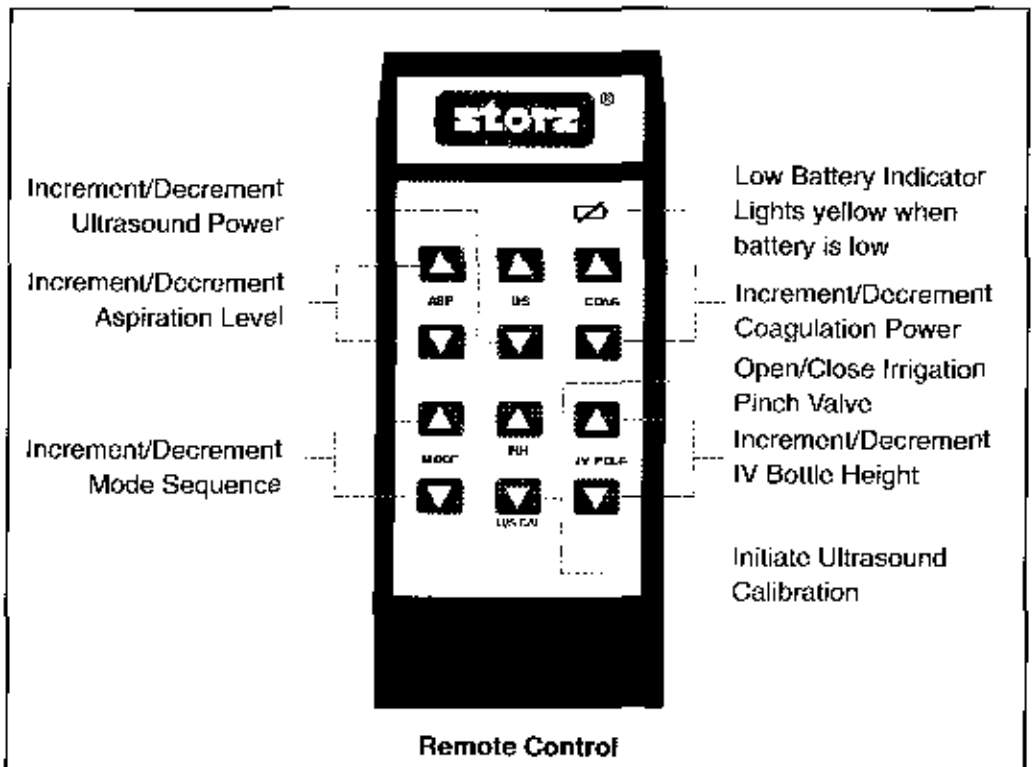


Figure 4–4. Remote Control Button Locations.

4.6. IAV Venturi Module.

The ***Storz Millennium™ Microsurgical System's IAV Venturi Module*** requires an external filtered medical grade air or medical grade nitrogen input with pressure between 80 and 100 psig. The input air supply must have a dew point of 35°F (1.6°C), and be oil–free, aerosol particle filtered and solid particle filtered to 5 microns. A pressure relief valve is included in the module to circumvent over pressure input conditions.

Irrigation–Aspiration Mode

Irrigation

With your ***Storz Millennium™ Microsurgical System*** in the ***anterior*** mode, a single irrigation line is controlled via a pinch valve on the front of the IAV Venturi module. The irrigation line from an inverted bottle of balanced salt solution is attached through the pinch valve to the surgical handpiece. The delivery pressure of the balanced salt solution is adjusted by varying the height of the bottle in relation to the patient's eye (for bottle infusion see page 4–56). On/off control of irrigation is accomplished through the footpedal, or via the touch screen.

NOTE: *See page 4–10 for irrigation control.*

With your ***Storz Millennium™ Microsurgical System*** in ***posterior*** mode, the irrigation line does not pass through the pinch valve. The delivery pressure of the balanced salt solution is adjusted by varying the height of the bottle in relation to the patient's eye, and on/off control is via the roller clamp on the administration line or the stopcock.

Irrigation/Aspiration

The IAV Venturi Module will provide vacuum levels from 15 mmHg up to 550 mmHg in 1 mmHg increments depending upon the mode of operation. Aspiration limits are set via the touch screen and controlled via the foot controller

(as explained on page 4–10), the remote control, or rocker switch if programmed.

In the anterior mode, irrigation only takes place in region 1 of footpedal travel, and both irrigation and aspiration take place in region 2 of footpedal travel.

Capsule Polish

The capsule polish function is typically accomplished with a lower vacuum setting than standard settings. These settings may be customized to allow quick entry into a lower vacuum level as explained in chapter 3.

Viscoelastic Removal

Viscoelastic removal is typically accomplished with a lower vacuum setting than standard. These settings may be customized to allow quick entry into a lower vacuum level as explained in chapter 3.

Linear Vacuum

This function is identical to the *irrigation/aspiration* function explained above. These settings may be customized to allow quick entry into a second vacuum level.

Reflux

Aspiration is applied to the collection cassette and subsequently to the handpiece via a tubing set. Reflux applies a momentary reverse pressure through the aspiration line to clear the aspiration port of lodged material. Reflux may be programmed for *single*, *repeat*, or *none*. If enabled, the reflux feature is applied with inward movement of the footpedal in all aspiration modes. Rotating the footpedal inward initiates the reflux cycle, releasing it completes the cycle.

WARNING: For optimum aspiration and reflux performance, the Storz Millennium™ Microsurgical System cassette aspiration port must be placed at the same level as the patient's eye, with no more than 7 cm (3 in) differential.

- *Tubing must not be pulled taut–it must be allowed to have a droop or sag between the cassette and the handpiece.*
- *Whenever the cassette is ejected from the system console, always keep the handpiece above the level of the cassette port.*
- *Do not use continuous reflux for more than 5 seconds. Any continuous reflux must be interrupted by a few seconds of aspiration.*

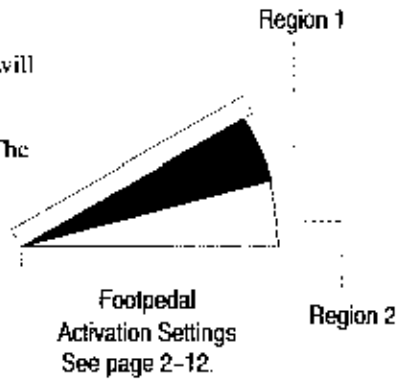
***NOTE:** See chapter 3 to program the footpedal for left footed operation.*

Foot Control of Irrigation/Aspiration

As the footpedal is initially pressed, the irrigation control valve will open to allow irrigation into the eye.

Once irrigation has been initiated and the footpedal has been depressed approximately 5 degrees (or as programmed), a momentary increase in footpedal resistance will be noted signifying the transition from region 1 to region 2 and the start of aspiration. Aspiration increases proportional to footpedal travel with the maximum level being set via the **MAX VACUUM** input on the touch screen. Region 2 will provide linear control of aspiration. The **ACTUAL VACUUM** display will indicate the current aspiration level.

If enabled, an audible linear tone will indicate aspiration. The pitch of the tone increases with increased aspiration.



Vacuum Response

Vacuum response refers to the amount of time required to obtain the desired aspiration level. A fast response value instructs the system to achieve the desired aspiration level in the shortest amount of time; similarly, slow indicates that the time to achieve the desired aspiration will be much longer. The response can be changed by choosing **TOOLS** and the selecting **VACUUM RESPONSE** *(See figure 4–5)*. Use the slide control to select the desired response.

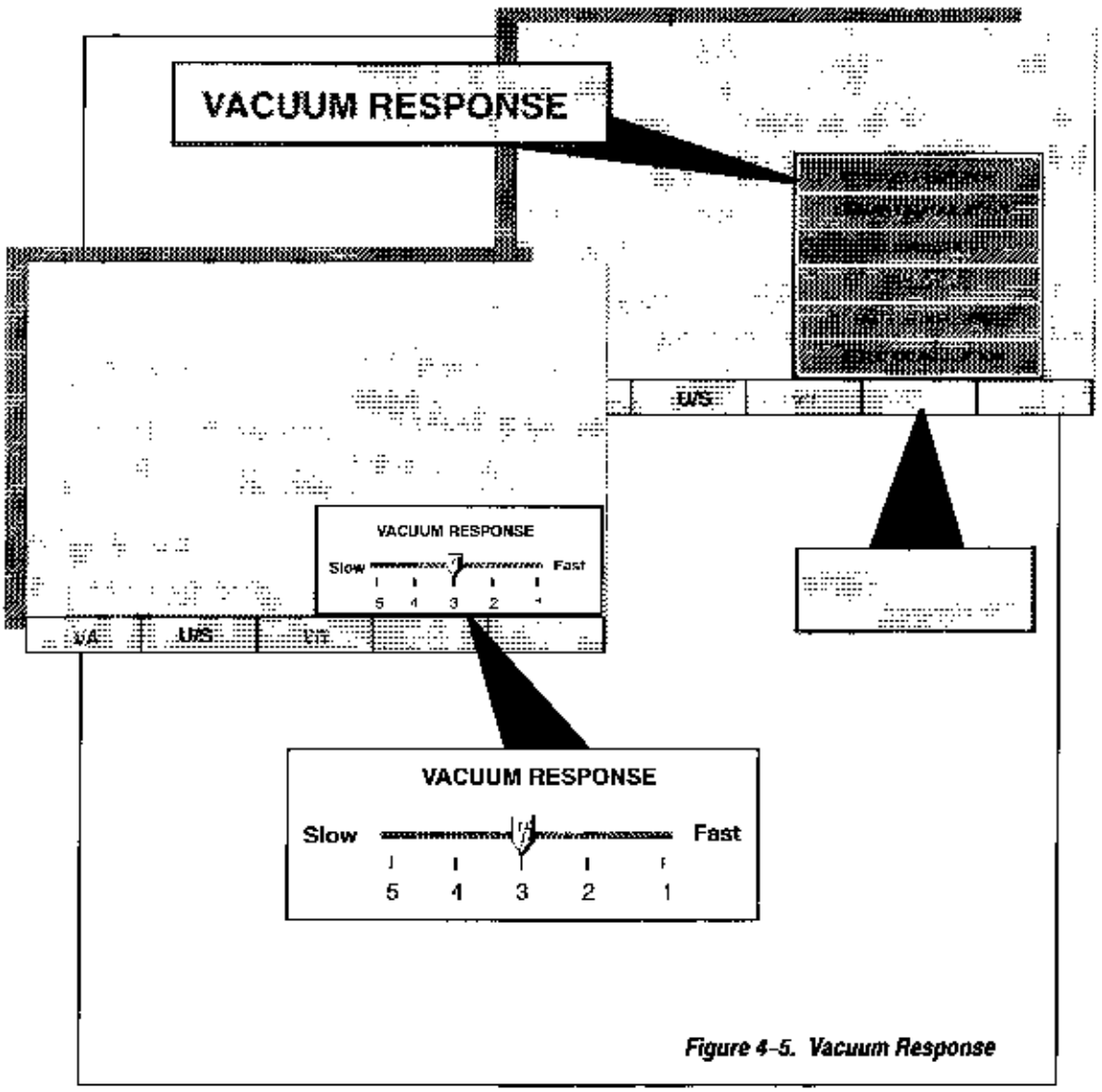


Figure 4–5. Vacuum Response

Venturi Irrigation/Aspiration Set–up And Use.

Refer to figure 4–6 for the following steps.

A. Connect the air source to the connector at the rear of the base unit.

B. Connect a luer adaptor tube set to the back of the I/A handpiece.

C. If a soft sleeve I/A handpiece is being used, thread the blue irrigation sleeve onto the handpiece tip.

D. Connect the green irrigation line and the clear aspiration line of the I/A tubing set to the handpiece luer adaptor tube set.

E. Connect the irrigation administrative set to the green irrigation line of the I/A tubing set.

F. Insert the cassette into the console until it locks in place.

G. Securely lock the aspiration connector of the aspiration line to the cassette connector.

H. Open the pinch valve by pressing **IRR OFF**, insert the green irrigation line of the I/A tubing set into the groove of the pinch valve. Press **IRR ON** to close the pinch valve.

I. Spike and hang a bottle of irrigating solution to the irrigation administration set. Assure the roller clamp is closed.

J. The external components of your system are now ready. Go to step K on page 4–14 to set the operating parameters.

WARNING: For optimum aspiration and reflux performance, the Storz Millennium™ Microsurgical System cassette aspiration port must be placed at the same level as the patient's eye, with no more than 7 cm (3 in) differential.

WARNING:
Assure the handpiece and accessories are sterilized before use as specified.

NOTE:
The holes in the irrigation sleeve should be placed perpendicular to the port on the handpiece tip.

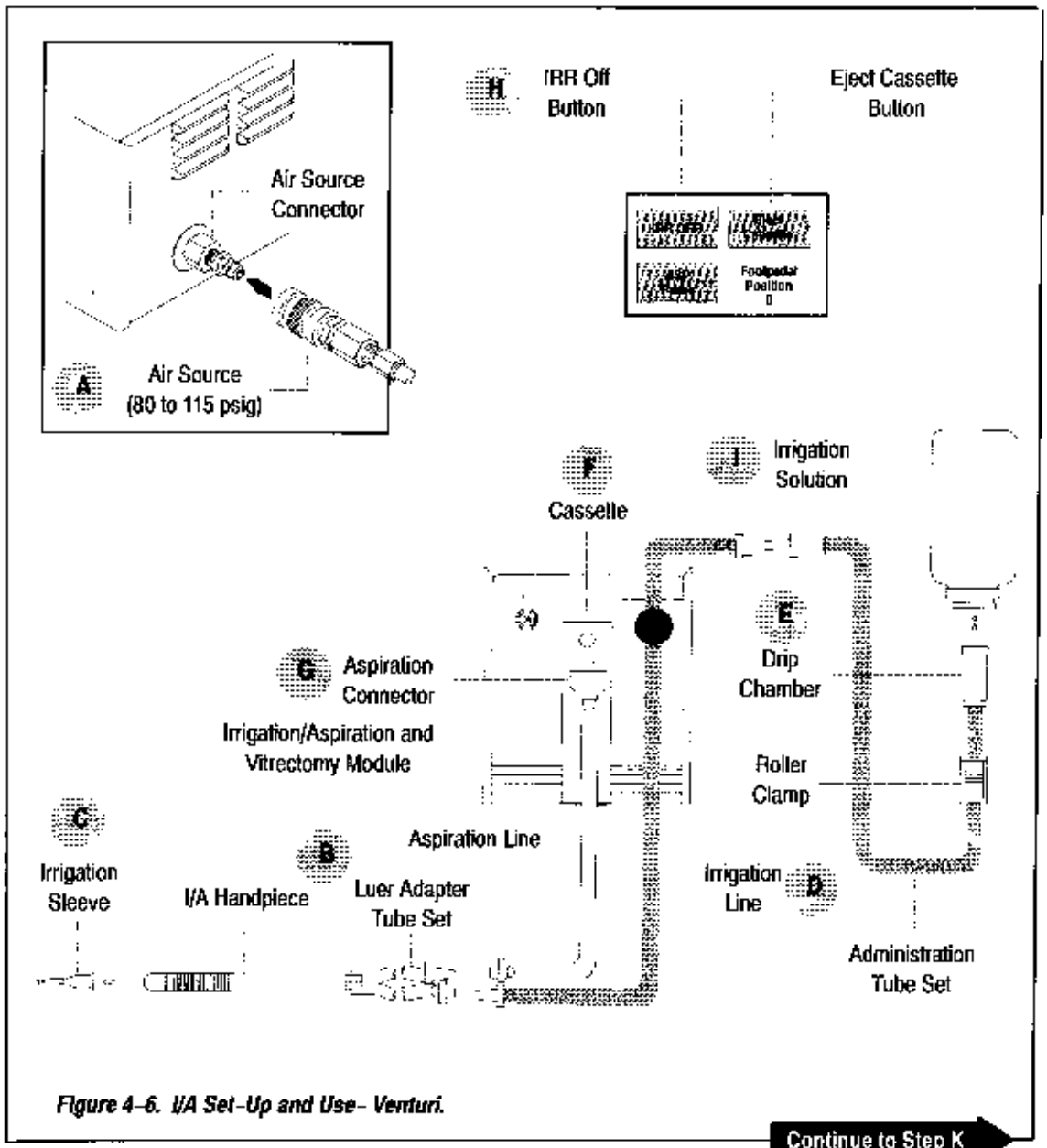


Figure 4–6. I/A Set-Up and Use– Venturi.

Continue to Step K

Refer to ***figure 4–6*** *for the following steps.*

K. Press the ***I/A*** tab on the surgical mode screen. The tab will expand.

L. Select the desired mode from the expanded tabs. The aspiration mode screen will be displayed.

M. Use the spin buttons to set the desired aspiration vacuum.

N. Squeeze and release the drip chamber until chamber is 1/2 filled with solution, and then release the roller clamp.

O. Select **ASP Prime**. (the irrigation line will automatically be primed). Allow solution to flow until it reaches the I/A handpiece or until all air has been removed from the irrigation line.

P. Confirm that irrigation and aspiration are balanced by pinching the irrigation line and observing that the test chamber dimples.

Q. Select **ASP Prime** again to turn off priming mode.

R. The handpiece is now ready for use.

WARNING: For optimum aspiration and reflux performance, the Storz Millennium™ Microsurgical System cassette aspiration port must be placed at the same level as the patient's eye, with no more than 7 cm (3 in) differential.

NOTE:
Hold the handpiece tip towards the ceiling while priming the irrigation line to insure all air has been removed.

NOTE:
See chapter 5 for cleaning and sterilization requirements when surgery is completed.

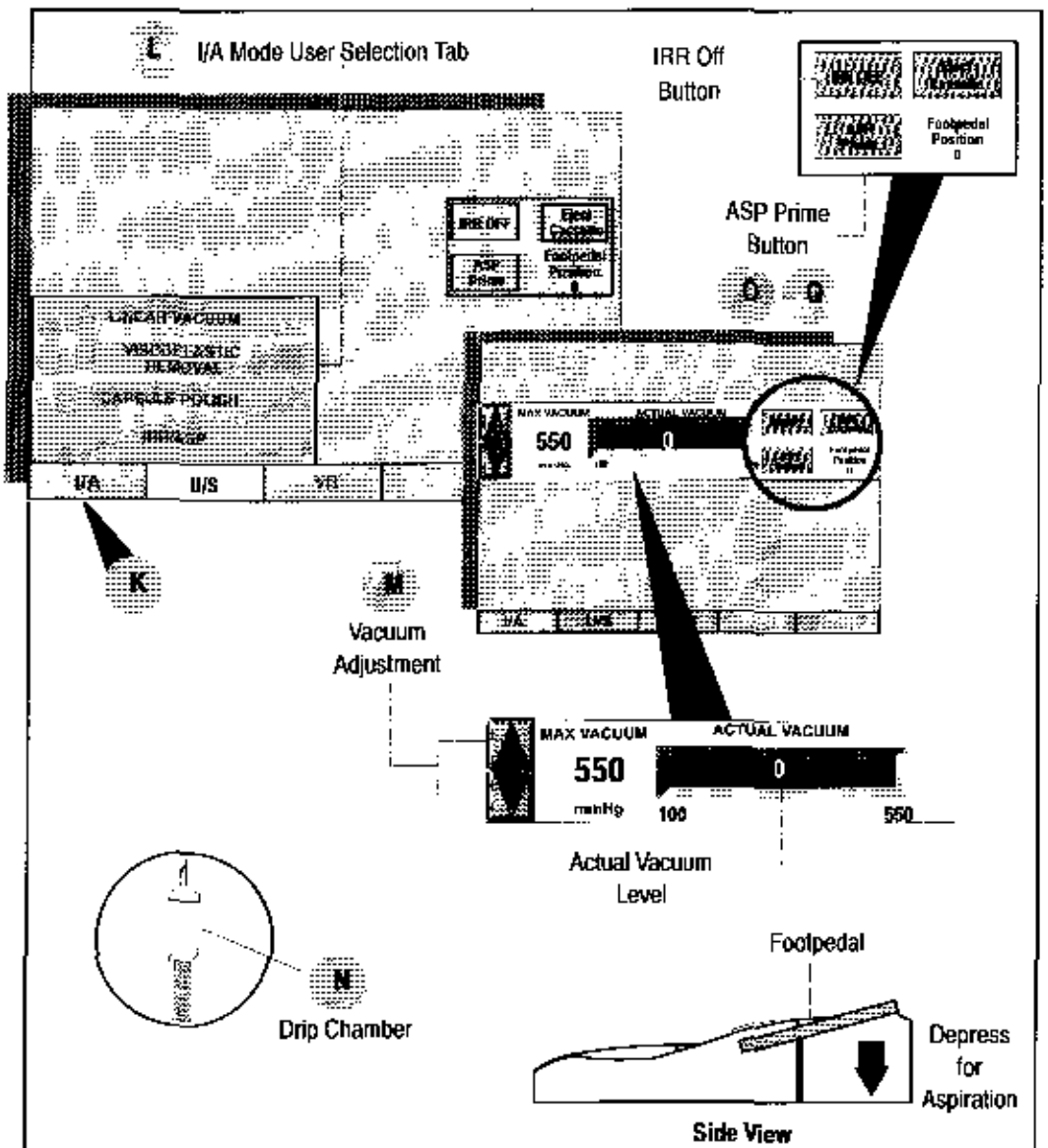


Figure 4–6. I/A Set-Up and Use– Venturi.

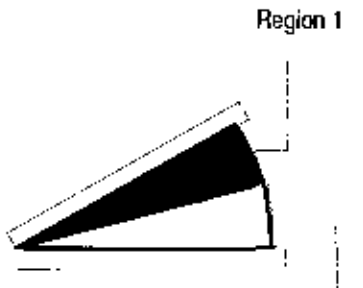
Vitrectomy Mode

The vitrectomy procedure is performed with a pneumatically operated guillotine type cutter that draws the vitreous material into the port. The vitreous is then cut and aspirated into the disposable collection container through the attached tubing.

Foot Control Of Anterior Vitrectomy Mode

As the footpedal is initially pressed, the irrigation control valve will open to allow irrigation into the eye (anterior mode only).

Once irrigation has been initiated and the footpedal has been depressed approximately 5 degrees (or as programmed), a momentary increase in footpedal resistance will be noted signifying the transition from region 1 to region 2 and the start of aspiration. Aspiration increases proportional to footpedal travel with the maximum level being set via the **MAX VACUUM** input on the touch screen. Region 2 will provide linear control of aspiration. The **ACTUAL VACUUM** display will indicate the current aspiration level.



Anterior Footpedal Activation Settings
See page 2-12.

If enabled, an audible linear tone will indicate aspiration. The pitch of the tone increases with increased aspiration.

A **VIT CUTTER DISABLED** or **VIT CUTTER ENABLED** message will be presented on the screen to advise the user whether the vitrectomy feature is activated. The cutter is activated by outward travel of the footpedal.

Foot Control Of Posterior Vitrectomy Mode

In the posterior mode, irrigation is not controlled by the system. Aspiration increases proportional to footpedal travel with the maximum level being set via the **MAX VACUUM** input on the touch screen. The **ACTUAL VACUUM** display will indicate the current aspiration level.

If enabled, an audible linear tone will indicate aspiration. The pitch of the tone increases with increased aspiration.

A **VIT CUTTER DISABLED** or **VIT CUTTER ENABLED** message will be presented on the screen to advise the user whether the vitrectomy feature is activated. The cutter is activated by outward travel of the footpedal.

Operating Modes

The ***Storz Millennium™ Microsurgical System's IAV Venturi Module*** supports a single aspiration port driven from a venturi pump located within the module. The pump requires an external gas/air source with pressure between 80 and 100 PSIG with a dew point of 35°F (1.6°C). The air must be oil–free, aerosol particle filtered, and solid particle filtered to 5 microns. Either fixed or linear aspiration control may be selected. The control may be adjusted from 5 mmHg to 550 mmHg vacuum in 1 mmHg increments utilizing the up/down **VIT CUTTER** spin buttons.

Irrigation, in the anterior mode, is supported by a single gravity fed irrigation system in which the irrigation tubing is routed through a pinch valve. Reflux (if enabled) is by inward yaw movement of the footpedal.

The venturi module provides two vitrectomy cutter modes:

- *Linear Cut Linear Vacuum* The control may be adjusted to provide a cutting speed from 30 to 750 cuts per minute in 30 cuts per minute increments utilizing the up/down spin buttons, or 1cut per minute utilizing the numeric keypad. Outward yaw movement provides linear control of the cut rate as a function of footpedal displacement. When the footpedal is released, it returns to center and the cutter is disabled. The actual cut rate is displayed.
- *Fixed Cut Linear Vacuum* The control may be adjusted to provide a cutting speed from 30 to 750 cuts per minute in 30 cuts

NOTE: For explanation of dual linear foot control see page 2–13.

NOTE: Cut rate may be changed by 1 cut per minute utilizing the numeric keypad.

per minute increments utilizing the up/down spin buttons, or 1cut per minute utilizing the numeric keypad. Each successive outward yaw movement toggles the cutter ON or OFF. The actual cut rate is displayed.

WARNING: For optimum aspiration and reflux performance, the Storz Millennium™ Microsurgical System cassette aspiration port must be placed at the same level as the patient's eye, with no more than 7 cm (3 in) differential.

Anterior Vitrectomy Set–up And Use – Venturi

Refer to figure 4–7 for the following steps.

A. Connect the air source to the connector at the rear of the base unit.

B. Connect the blue air line from the handpiece to the vitrectomy port on the IAV Venturi Module.

C. Connect the green irrigation line and the clear aspiration line to the appropriate luer connector on the vitrectomy cutter.

D. Connect the male luer connector on the clear aspiration line to the cassette luer connector.

E. Insert the cassette into the machine until it locks into place.

F. Open the pinch valve by pressing **IRR OFF**. Insert the green irrigation line from the handpiece into the groove of the pinch valve. Press **IRR ON** to close the pinch valve.

G. Spike and hang a bottle of irrigating solution to the irrigation administration set. Assure the roller clamp is closed.

H. The external components of your system are now ready. Go to step I on page 4–20 to set the operating parameters.

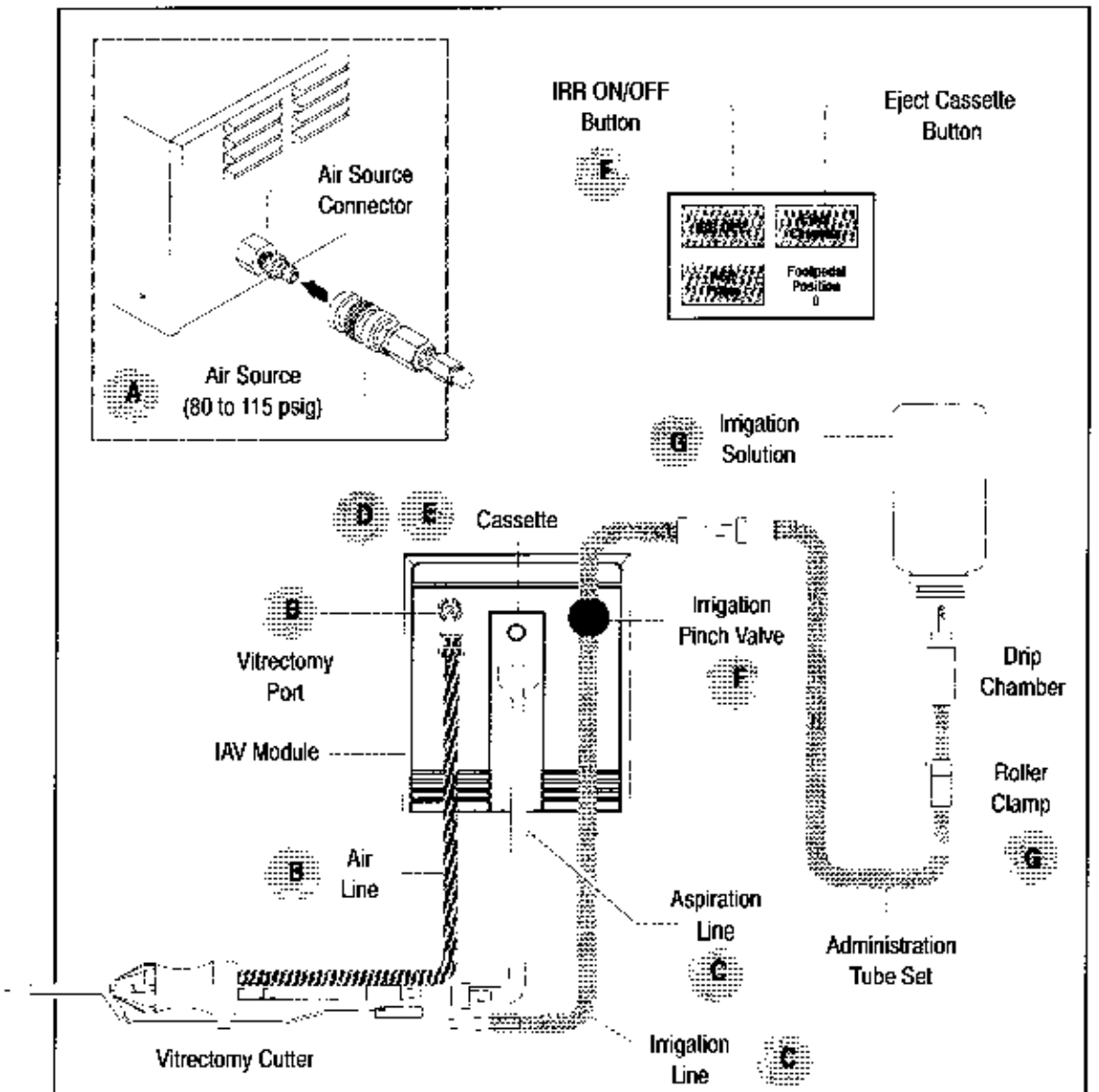


Figure 4–7. Anterior Vitrectomy Set-Up and Use – Venturi.

Continue to Step I

*Refer to **figure 4–7** for the following steps.*

I. Press the **VIT** tab on the surgical mode screen. The tab will expand.

J. Select the desired vacuum mode from the expanded tabs. The vacuum and cutter screens will be displayed.

K. Use the spin buttons to set the desired vacuum level and cut rate.

L. Close the roller clamp. Squeeze and release the drip chamber until it is 1/2 filled with solution.

M. Immerse the vitrectomy cutter tip into a small, sterile container of irrigating solution, and open the roller clamp.

N. Select **ASP Prime**. (the irrigation line will automatically be primed). Aspirate fluid until the flow of solution reaches the cassette, or until all air has been removed from the irrigation and aspiration lines.

O. Select **ASP Prime** again to turn off priming mode.

P. Rotate the footpedal outward to toggle the cutter on and off, and depress the footpedal for aspiration. **VIT CUTTER ENABLED/DISABLED** will be displayed on the screen.

Q. A tone will signify cutter operation (if enabled).

R. For reflux (if enabled), rotate the footpedal in the inward direction.

***NOTE:** For explanation of dual linear foot control see page 2–13.*

***NOTE:** See chapter 3 to program the footpedal for left footed operation.*

NOTE:
See chapter 3 page 3–8 for setting audio levels.

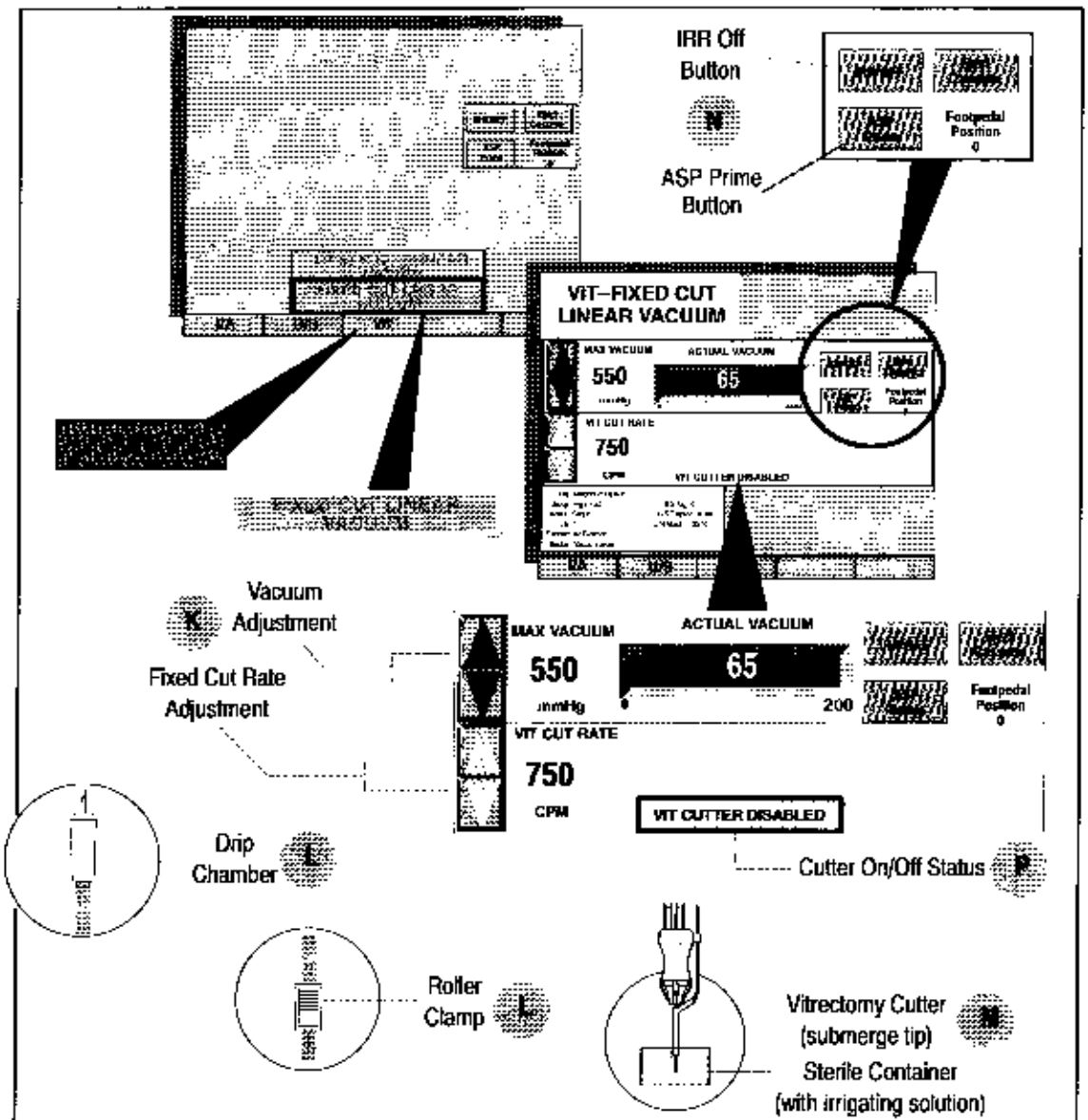


Figure 4–7. Anterior Vitrectomy Set–Up and Use – Venturi.

Continue to Next Page

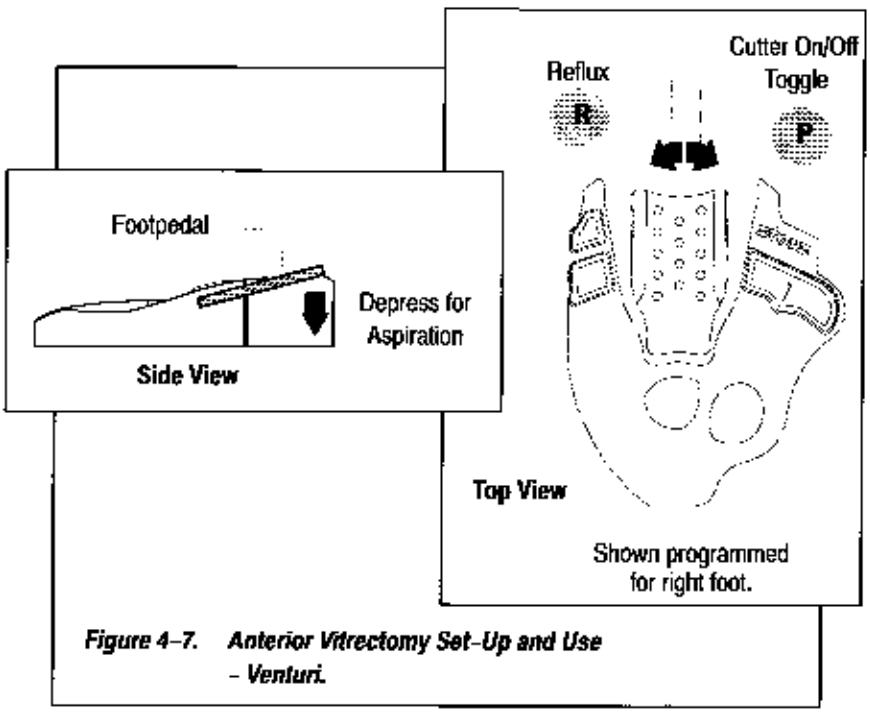


Figure 4–7. Anterior Vitrectomy Set–Up and Use – Venturi.

Posterior Vitrectomy Set–up and Use – Venturi.

Refer to ***figure 4–8*** *for the following steps.*

A. Connect the air source to the connector on the rear of the module.

B. Separate the connector located within the clear aspiration line of the vitrectomy cutter tubing set. Insert a stopcock between the connectors. Attach a syringe to the stop cock. Turn stopcock valve to shut off syringe.

C. Securely lock the male connector on the clear aspiration line from the stopcock onto the luer connector on the cassette.

D. Connect the blue air line to the vitrectomy port on the tAV Venturi Module.

E. Insert the cassette into the machine until it locks into place. When entering the posterior mode the cassette is automatically ejected and the message "**Verify Yellow Cassette Is Inserted**" is displayed. Assure that the correct cassette is present and reinsert it until it locks into place.

F. Connect the infusion cannula to one end of the irrigation line. *Connect a three–way stopcock to the other end.*

G. Connect the irrigation administration set to the stopcock on the irrigation line. Turn the stopcock to block the open port.

H. Close the roller clamp to the administration tube set. Spike and hang a bottle of irrigating solution.

I. The external components of your system are now ready. Go to step J on page 4–25 to set the operating parameters.

NOTE: If fragmentation, extrusion, or another secondary aspiration device will be used, disconnect the syringe and replace with the desired device.

WARNING: For optimum aspiration and reflux performance, the Storz Millennium™ Microsurgical System cassette aspiration port must be placed at the same level as the patient's eye, with no more than 7 cm (3 in) differential.

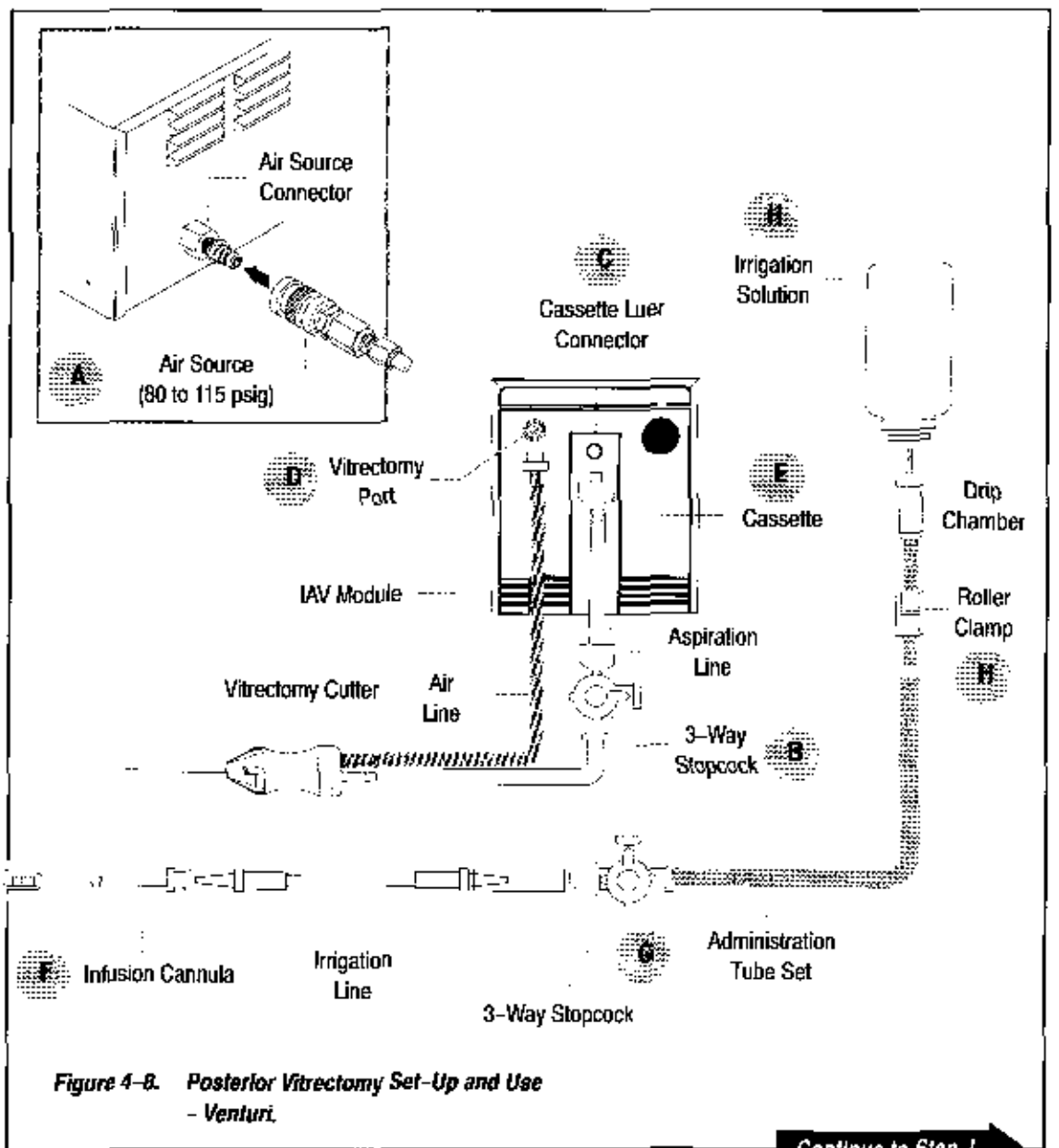


Figure 4–8. Posterior Vitrectomy Set-Up and Use – Venturi

NOTE: When entering the posterior mode the cassette is automatically ejected and the message "**Verify Yellow Cassette Is Inserted**" is displayed. Assure that the correct cassette is present and reinsert it until it locks into place.

*Refer to **figure 4–8** for the following steps.*

J. Press the **VIT** tab on the surgical mode screen. The tab will expand.

K. Select the desired mode from the expanded tabs. The vacuum and cutter screens will be displayed.

L. Use the spin buttons to set the desired vacuum level and cut rate.

M. Close the roller clamp. Squeeze and release the drip chamber until 1/2 filled with solution.

N. Immerse the vitrectomy cutter tip into a small, sterile container containing irrigating solution.

O. Open the roller clamp on the irrigation administration set to allow solution to flow until it reaches the infusion cannula or until all air has been removed from the irrigation line. Fill a small sterile container with irrigating solution.

P. Close the roller clamp on the irrigation administration set to stop flow until ready for use.

Q. Select **ASP Prime.** (the irrigation line will automatically be primed). Aspirate fluid until the flow of solution reaches the cassette, or until all air has been removed from the irrigation and aspiration lines.

R. Select **ASP Prime** again to turn off priming mode.

S. Rotate the footpedal outward to toggle the cutter on and off, and depress the footpedal for aspiration. **VIT CUTTER ENABLED/DISABLED** will be displayed on the screen.

T. A tone will signify cutter operation (if enabled).

U. For reflux (if enabled), rotate the footpedal in the inward direction.

NOTE: For explanation of dual linear foot control *see page 2–13.*

NOTE:
See chapter 3 page 3–8 for setting audio levels.

NOTE: See chapter 3 to program the footpedal for left footed operation.

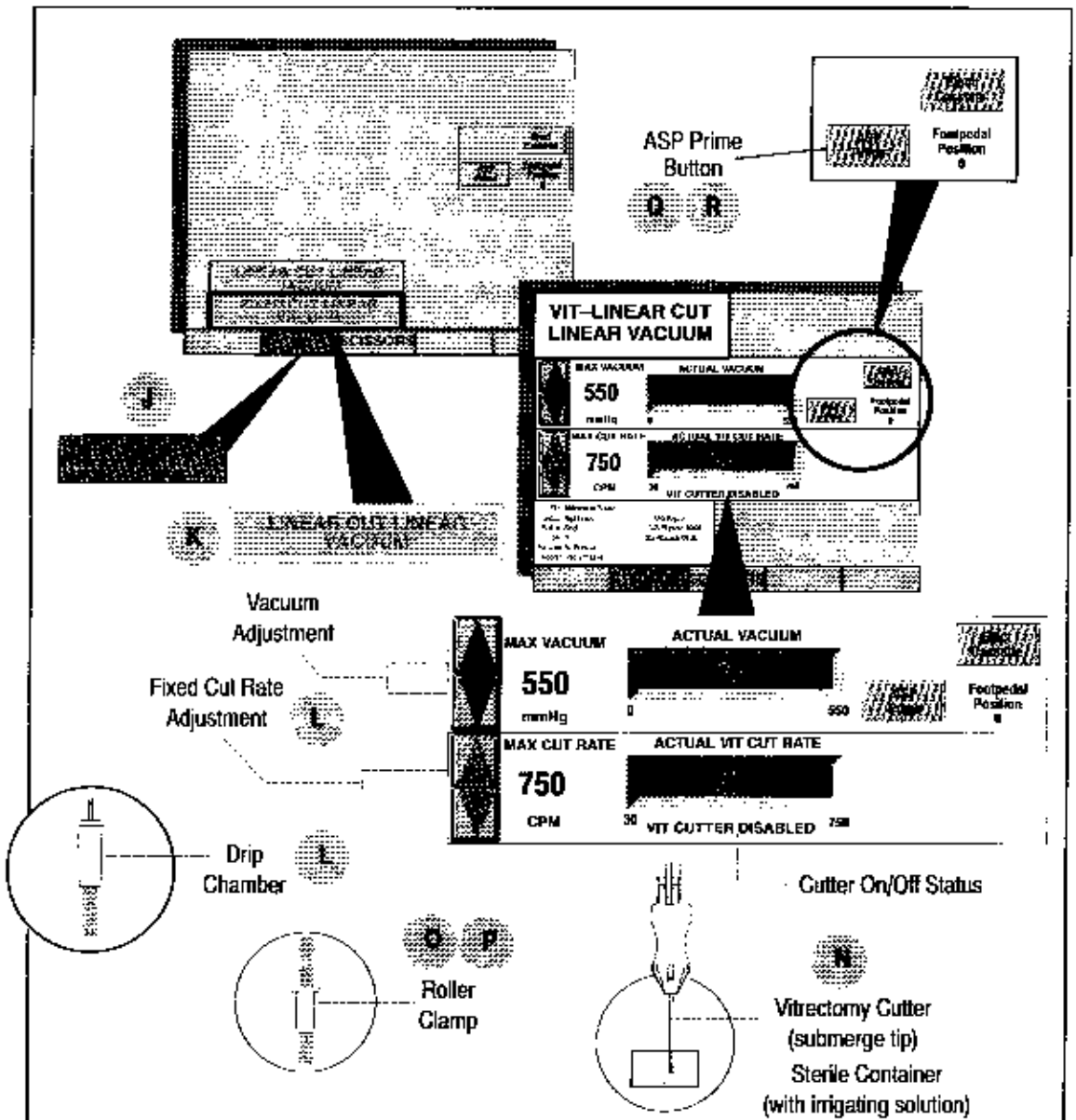


Figure 4–8. Posterior Vitrectomy Set–Up and Use – Venturi.

Continue On Next Page

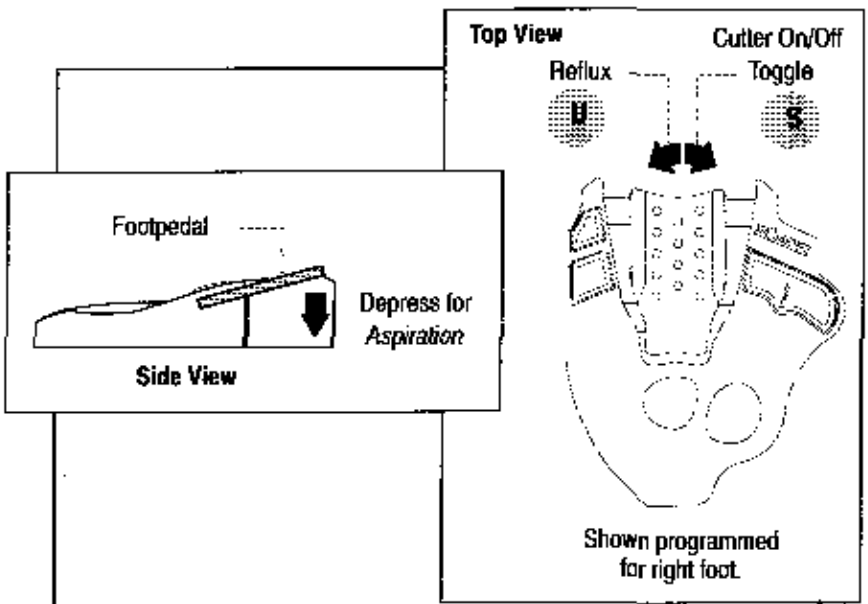


Figure 4–8. Posterior Vitrectomy Set-Up and Use – Venturi.

4.7. *Ultrasound Module*

Ultrasound Module Description

Phacoemulsification and phacofragmentation refer to the process of ultrasonic disintegration of the lens using a vibrating needle operating at a frequency above the audio range. Phacoemulsification refers to an anterior chamber procedure, and phacofragmentation refers to a posterior chamber procedure. The ***Storz Millennium™ Microsurgical System*** *Ultrasound Module* is available as a single port phacoemulsification module, a single port phacofragmentation module, or a dual port module which supports both. The electrical connections are identified by a white ring for phacoemulsification and a yellow ring for phacofragmentation.

The ultrasound display has up/down spin buttons for adjusting maximum ultrasound power and pulses per second. A progress bar indicates the actual ultrasound power. Average ultrasound power is displayed in the system status window. The ultrasound operational screen also displays the elapsed ultrasound time, and provides push buttons for one–step ul trasound calibration of the ultrasound handpiece. Select **END OF CASE RESET** in the **UTILS** tabs to reset the elapsed time.

The ***Storz Millennium™ Microsurgical System*** *Ultrasound Module* provides ultrasound operation in either continuous or pulsed modes by setting the PPS to zero or non–zero (or from the foot controller when so programmed) at any time during operation. The foot control operation and six ultrasound modes are explained in the following paragraphs.

Pulsed Ultrasound Mode

Pulsed Ultrasound power may be adjusted from 0% to 100% in 1% increments using the up/down spin buttons. When the pulse rate is set to zero, continuous ultrasound power will be enabled. Pulse output control is programmable from 1 to 20 pulses per second in 1 pulse per second ***(PPS)*** increments. In

dual linear mode with the pulse rate set to non–zero, pressing the footpedal into the U/S region activates pulsed ultrasound. In single linear modes, with the pulse rate set to non–zero, moving the footpedal in the outward yaw direction activates pulsed ultrasound.

The pulse rate control does not adjust the ultrasound power. The control adjusts the number of cycles of ultrasound power that occur during a one second time interval. In ***Pulsed Ultrasound Mode***, the phaco/frag handpieces are energized for one half of each time interval as defined by the ***PPS*** setting.

Irrigation/Aspiration in Ultrasound Mode

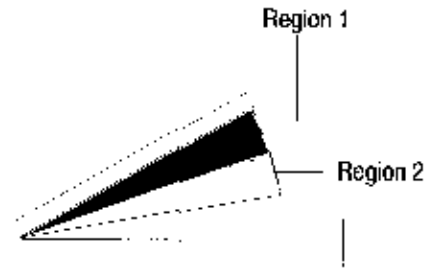
Aspiration in the ***phacoemulsification or phacofragmentation*** mode is accomplished with the ultrasound handpiece *(see figure 4 9 on page 4 34)*. Irrigation from the handpiece (phacoemulsification only) is applied to the eye through a silicone rubber sleeve that is placed over the ultrasound needle. The lens fragments are aspirated out of the eye through the center of the needle. Maximum aspiration in both the anterior and posterior modes is 400 mmHg. If the aspiration line becomes clogged, ***Reflux*** can be actuated by inward yaw footpedal movement.

WARNING: For optimum aspiration and reflux performance, the Storz Millennium™ Microsurgical System cassette aspiration port must be placed at the same level as the patient's eye, with no more than 7 cm (3 in) differential.

Ultrasound Mode

The application of ultrasound power is proportionally controlled by the footpedal between zero and the maximum limit set on the console.

Ultrasound power may be adjusted from 0% to 100% in 1% increments. The ultrasound output will be activated at the *minimum programmed power level as the footpedal moves* into the active ultrasound region, and will increase to the maximum programmed output as a function of linear footpedal travel.



FootPedal Activation Settings

See page 2-12.

ANTERIOR

Footpedal Operation In Anterior Single Linear Ultrasound Mode

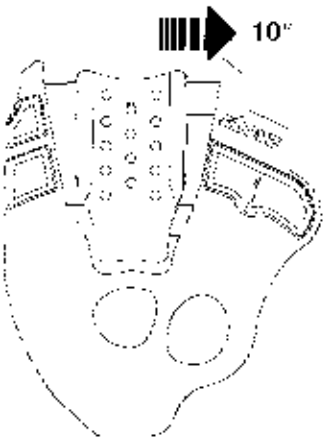
Irrigation is activated by region 1 of footpedal travel. As the footpedal travels through region 1, the irrigation pinch valve will open to apply irrigation to the eye. No aspiration or ultrasound power will be developed in region 1 of footpedal travel.

Aspiration is activated by region 2 of footpedal travel. A momentary increase in footpedal resistance will be noted signifying the transition from region 1 to region 2, and the start of aspiration. Fixed aspiration will be developed at the selected aspiration level. The screen will display the actual amount of aspiration.

Ultrasound power is activated by region 3 of footpedal travel. Another momentary increase in footpedal resistance will be noted signifying the transition from one region to the next, and the start of ultrasound power. Linear ultrasound power will be initiated and controlled as described previously. Pulsed ultrasound may be toggled on/off by moving the foot pedal in the outward yaw direction.

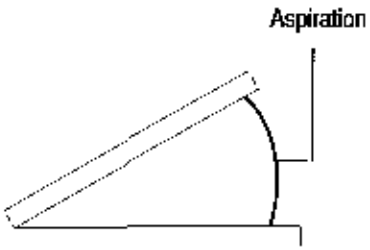
Dual Linear With Yaw Aspiration

The footpedal operates as described above, but additional aspiration is available using outward yaw movement.



Shown programmed for right foot.

DUAL LINEAR PHACO CONTROL



FootPedal Activation Settings See page 2-13.

POSTERIOR

Footpedal Operation In Anterior Dual Linear Ultrasound Mode

Irrigation is activated by region 1 of footpedal travel. As the footpedal travels through region 1, the irrigation pinch valve will open to apply irrigation to the eye. No aspiration or ultrasound power will be developed in region 1 of footpedal travel.

Aspiration is activated by region 2 of footpedal travel. A momentary increase in footpedal resistance will be noted signifying the transition from region 1 to region 2, and the start of aspiration. In region 2, linear aspiration will be developed at the selected aspiration level. The screen will display the actual amount of aspiration.

Footpedal travel in the outward yaw direction provides ultrasound power. Linear ultrasound power will be initiated and controlled as described previously.

Footpedal Operation in Posterior Ultrasound Mode

Aspiration is activated by footpedal travel in the pitch direction and footpedal travel in the outward yaw direction provides ultrasound power. Linear ultrasound power will be initiated and controlled as described previously.

Linear Vacuum

The ultrasound linear vacuum selection is a dual–linear function that provides both linear control of aspiration and ultrasound power. Aspiration is controlled in the pitch direction and ultrasound is controlled in the outward yaw direction. Vacuum and ultrasound power should be programmed as appropriate for the surgeon.

Fixed Vacuum

The ultrasound fixed vacuum selection is a single–linear function that provides fixed aspiration as the footpedal enters region 2 and linear control of ultrasound power in region 3. Vacuum and ultrasound power should be programmed as appropriate for the surgeon.

Dual Linear Segment Removal

The ultrasound dual–linear segment removal selection is a dual–linear function that provides both linear control of aspiration and ultrasound power. Aspiration is controlled in the pitch direction and ultrasound is controlled in the outward yaw direction. Vacuum and ultrasound power should be programmed as appropriate for the surgeon.

NOTE: Dual Linear Segment Removal, Dual Linear Sculpt, Segment Removal, and Sculpt can be reprogrammed for either dual linear or single linear operation and may be renamed as desired.

Dual–Linear Sculpt

The ultrasound dual–linear sculpt selection is a dual–linear function that provides both linear control of aspiration and ultrasound power. Aspiration is controlled in the pitch direction and ultrasound is controlled in the outward yaw direction. Vacuum and ultrasound power should be programmed as appropriate for the surgeon.

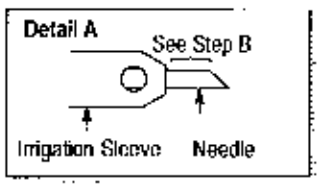
Segment Removal

The ultrasound segment removal selection is a single–linear function that provides fixed aspiration as the footpedal enters region 2 and linear control of ultrasound power in region 3. Vacuum and ultrasound power should be programmed as appropriate for the surgeon.

Sculpt

The ultrasound sculpt selection is a single–linear function that provides fixed aspiration as the footpedal enters region 2 and linear control of ultrasound power in region 3. Vacuum and ultrasound power should be programmed as appropriate for the surgeon.

WARNING:
Assure the handpiece and accessories are sterilized before use as specified.



CAUTION:
Allow 20 minutes for the handpiece to cool after sterilization before it is used. Electrical connector must be completely dry before connecting to module.

WARNING:
A loose needle may lead to improper calibration and could cause shedding of metal fragments into the eye.

WARNING: For optimum aspiration and reflux performance, the Storz Millennium™ Microsurgical System cassette aspiration port must be placed at the same level as the patient's eye, with no more than 7 cm (3 in) differential.

Phacoemulsification Set-Up – Venturi

Refer to ***figure 4–9*** *for the following steps. The ultrasound handpiece, needle, irrigation sleeve, and needle wrench must be sterilized before performing these steps.*

A. Thread and firmly secure the ultrasound needle onto the ultrasound handpiece using a needle wrench.

B. Thread the blue irrigation sleeve over the ultrasound needle so that the holes in the irrigation sleeve are placed approximately 1 mm from and perpendicular to the bevel of the ultrasound needle (increase to approximately 1.5 mm for denser cataracts) *(see detail A)*.

C. Connect the handpiece electrical line to the connector on the ultrasound module. Align the key on the handpiece connector with the key on the module connector.

D. Connect the air source to the connector on the rear of the IAV Venturi Module.

E. Connect the green irrigation line and the clear aspiration line to the appropriate luer connector on the ultrasound handpiece.

F. Connect the male luer connector on the clear aspiration line to the cassette luer connector.

G. Insert the cassette into the IAV Venturi Module until it locks into place.

H. Open the pinch valve by pressing **IRR OFF**. Insert the green irrigation line from the handpiece into the groove of the pinch valve. Press **IRR ON** to close the pinch valve, and connect to the irrigation administration tube set.

I. Spike and hang a bottle of irrigating solution to the administration tube set. Assure the roller clamp is closed.

J. The external components of your system are now ready. Go to step A on page 4–35 to set the operating parameters.

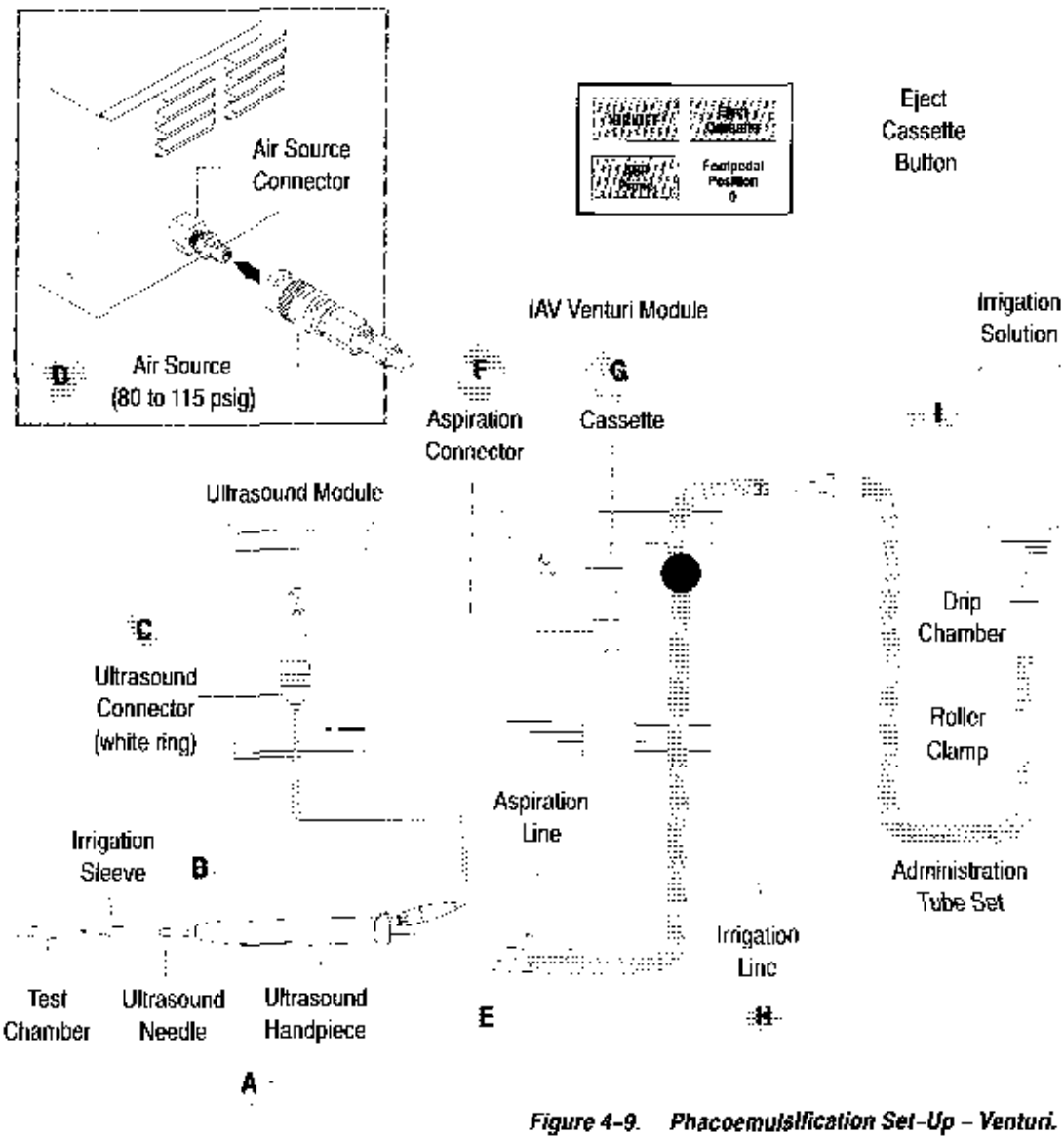


Figure 4-9. Phacoemulsification Set-Up – Venturi.

Continue to Step A , Page 4-35

NOTE: The ultrasound needle must be properly installed and not defective, and the irrigation and aspiration lines must be properly connected.

NOTE:
Hold the handpiece tip towards the ceiling while priming the irrigation line to insure all air has been removed.

Calibration Evaluation:

If calibration fails, check connections and needle, then attempt calibration a second time.

If calibration fails twice, change to a known good handpiece and attempt to calibrate again.

If a known good handpiece fails calibration, or if assistance is needed to determine if the original handpiece is defective, contact the Storz Instrument Company Technical Support Department (refer to paragraph 7.6 on page 7–14).

Phacoemulsification Operation

You have connected the external components of your Venturi Ultrasound system. Now you are ready to set the operating parameters. *See **figure 4–10** for the following steps.*

A. Press the **U/S** tab on the surgical mode screen. The tab will expand.

B. Select the desired mode from the expanded tabs. The aspiration and ultrasound mode screens will be displayed.

C. Use the spin buttons to set the desired aspiration level, and the ultrasound maximum power. You will also need to set the PPS for pulsed ultrasound.

D. Squeeze and release the drip chamber until chamber is 1/2 filled with solution, then release the roller clamp.

E. Press **IRR OFF** to open pinch valve. Fill test chamber with irrigating solution, and when full, slide over tip of ultrasound handpiece.

F. Select **U/S Calibrate,** (the irrigation and aspiration lines will be primed automatically).

G. The irrigation line followed by the aspiration line will be primed automatically. Assure all air bubbles are cleared from lines during priming. Once the system has been primed, ultrasound calibration will begin automatically, and ultrasound tone will sound. When complete, the **U/S Calibrate** stops blinking and returns to gray.

H. Confirm that irrigation and aspiration are balanced by pinching the irrigation line and observing that the test chamber dimples.

I. As a matter of operator convenience, priming is automatically canceled when calibration has been completed or cancelled. Recalibrate if either the handpiece or ultrasound needle is changed.

J. Your ***Storz Millennium ™ Microsurgical System** Ultrasound System* is now ready for use.

K. Press the footpedal to begin ultrasound operation. Aspiration and ultrasound power will be applied as the foot pedal enters their pre programmed regions (as described in chapter 3).

L. The **ACTUAL VACUUM** displays the vacuum being used in relation to the maximum setting. The **ACTUAL U/S** progress bar displays amount of ultrasound power being used in relation to the maximum setting. The ***Elapsed Time*** display indicates the time in minutes and seconds that ultrasound power has been energized.

NOTE:
See chapter 5 for cleaning and sterilization requirements when surgery is completed.

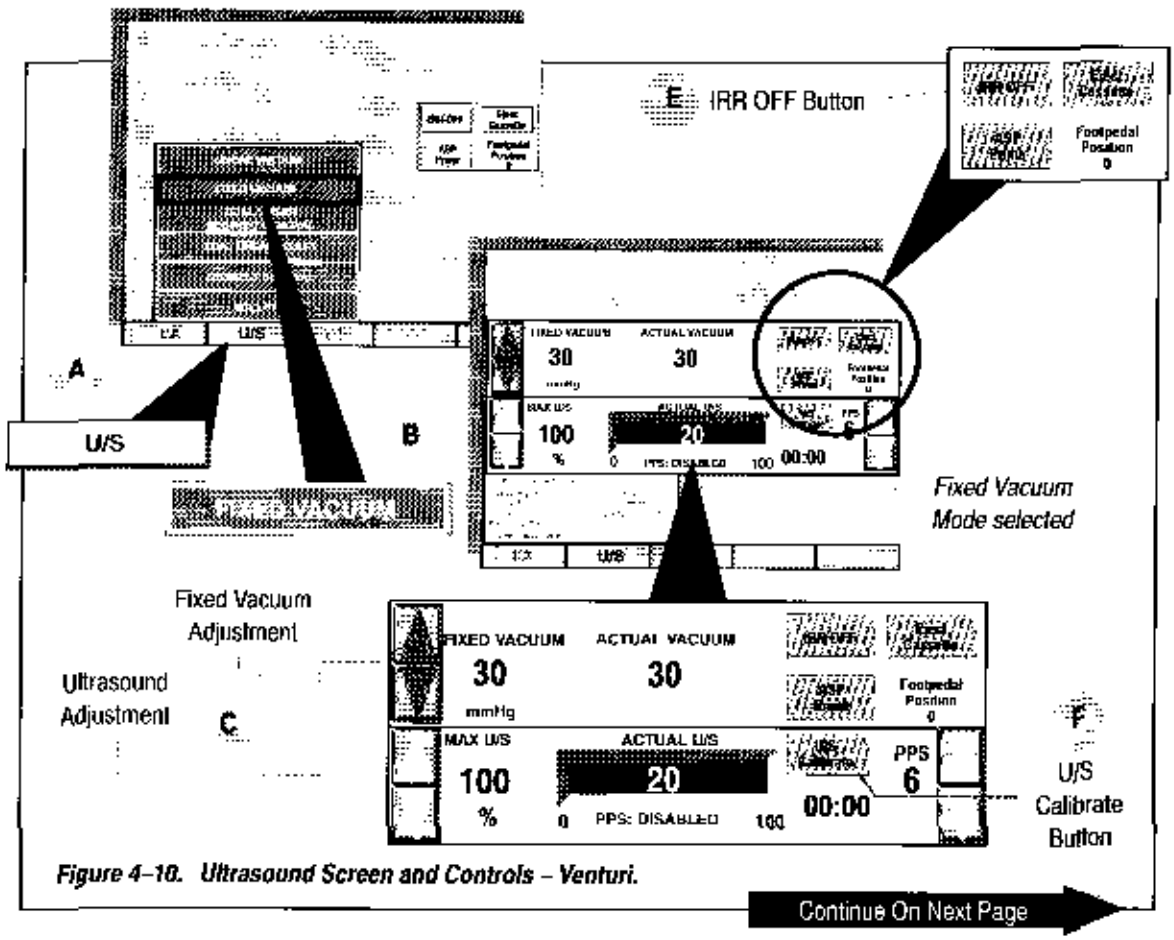


Figure 4–10. Ultrasound Screen and Controls – Venturi.

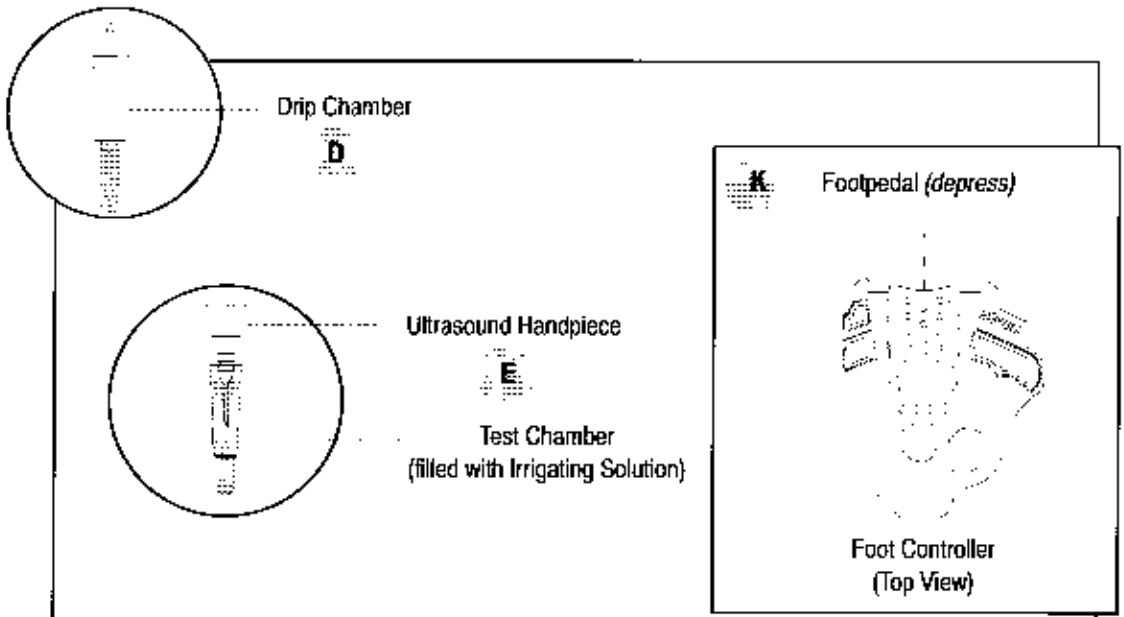


Figure 4–10. Ultrasound Screen and Controls – Venturi. (continued)

Phacofragmentation Handpiece Set–Up – Venturi

Refer to ***figure 4–11*** *for the following steps. The ultrasound handpiece, needle, and needle wrench must be sterilized before performing these steps.*

A. Thread and firmly secure the fragmentation needle onto the fragmentation handpiece using a needle wrench.

B. Connect the handpiece electrical connector to the yellow banded connector on the ultrasound module. Align the key on the electrical connector to the key on the module connector.

C. Connect the air source to the connector on the rear of the IAV Venturi Module.

D. Connect the clear aspiration line between the handpiece and the disposable cassette.

E. Insert the cassette into the IAV Venturi Module until it locks into place. When entering the posterior mode the cassette is automatically ejected and the message "**Verify Yellow Cassette Is Inserted**" is displayed. Assure that the correct cassette is present and reinsert it until it locks into place.

F. Connect the infusion cannula to one end of the irrigation line. Connect a three–way stopcock to the other end.

G. Connect the irrigation administration set to the stopcock on the irrigation line. Turn the stopcock to block the open port.

H. Close the roller clamp to the administration tube set. Spike and hang a bottle of irrigating solution.

I. The external components of your system are now ready. Go to step A on page 4–40 to set the operating parameters.

WARNING:
Assure the handpiece and accessories are sterilized before use as specified.

WARNING:
Allow 20 minutes for the handpiece to cool after sterilization before it is used.

WARNING:
A loose needle may lead to improper calibration and could cause shedding of metal fragments into the eye.

WARNING: For optimum aspiration and reflux performance, the Storz Millennium™ Microsurgical System cassette aspiration port must be placed at the same level as the patient's eye, with no more than 7 cm (3 in) differential.

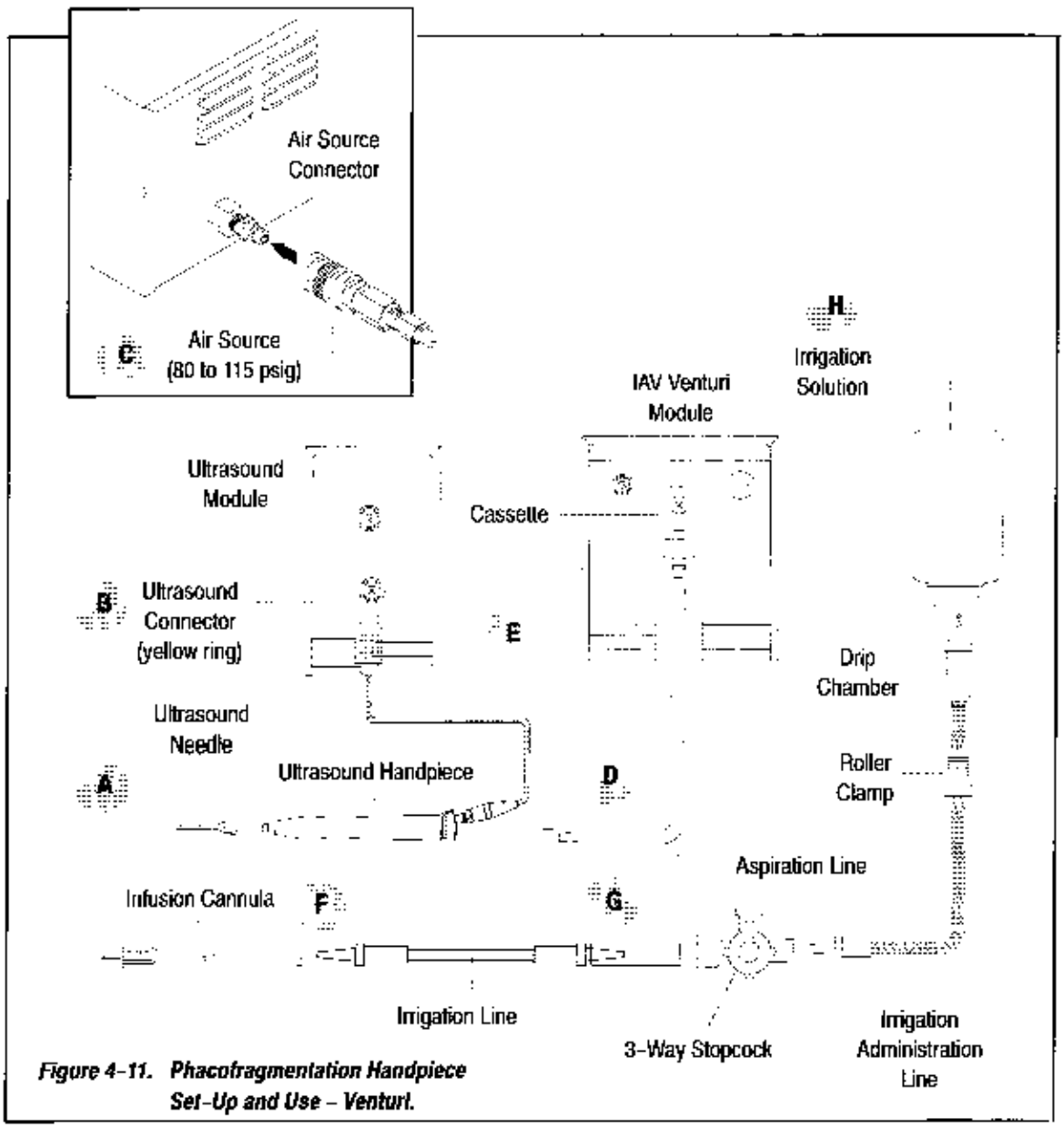


Figure 4–11. Phacofragmentation Handpiece Set-Up and Use – Venturi.

Phacofragmentation Operation

You have connected the external components of your Venturi Ultrasound system. Now you are ready to set the operating parameters. *Refer to figure 4–12 for the following steps.*

A. Press the **U/S** tab on the surgical mode screen. The tab will expand.

B. Select the desired mode from the expanded tabs. The aspiration and ultrasound mode screens will be displayed.

C. Use the spin buttons to set the desired aspiration level, and the ultrasound maximum power (and PPS for pulsed ultrasound).

D. Squeeze and release the drip chamber until chamber is 1/2 filled with solution, and then release the roller clamp.

E. Open the roller clamp of the irrigation administration set to the solution flow and allow the solution to flow until it reaches the infusion cannula or until all air has been removed from the irrigation line.

F. Immerse the fragmentation needle's tip into a small sterile container of irrigating solution.

G. Select **U/S Calibrate,** (the aspiration line will be primed automatically).

H. The aspiration line will be primed automatically. Assure all air bubbles are cleared from lines during priming. Once the system has been primed, ultrasound calibration will begin automatically.

I. As a matter of operator convenience, priming is automatically canceled when calibration is completed or canceled. Recalibrate if either the handpiece or ultrasound needle is changed.

J. Your ***Storz Millennium™ Microsurgical System*** *Ultrasound System* is now ready for use.

CAUTION:
Do not touch the handpiece needle at any time while ultrasound power is operating.

NOTE: When entering the posterior mode the cassette is automatically ejected and the message "**Verify Yellow Cassette Is Inserted**" is displayed. Assure that the correct cassette is present and reinsert it until it locks into place.

Calibration Evaluation:

If calibration fails, check connections and needle, then attempt calibration a second time.

If calibration fails twice, change to a known good handpiece and attempt to calibrate again.

If a known good handpiece fails calibration, or if assistance is needed to determine if the original handpiece is defective, contact the Storz Instrument Company Technical Support Department (refer to paragraph 7.6 on page 7–14).

K. Press the footpedal to begin ultrasound operation. Aspiration and ultrasound power will be applied as the footpedal enters their pre–programmed regions (as described in chapter 3).

L. The **ACTUAL VACUUM** displays the vacuum being used in relation to the maximum setting. The **ACTUAL U/S** progress bar displays amount of ultrasound power being used in relation to the maximum setting. The ***Elapsed Time*** display indicates the time in minutes and seconds that ultrasound power has been energized since last reset.

NOTE:
See chapter 5 for cleaning and sterilization requirements when surgery is completed.

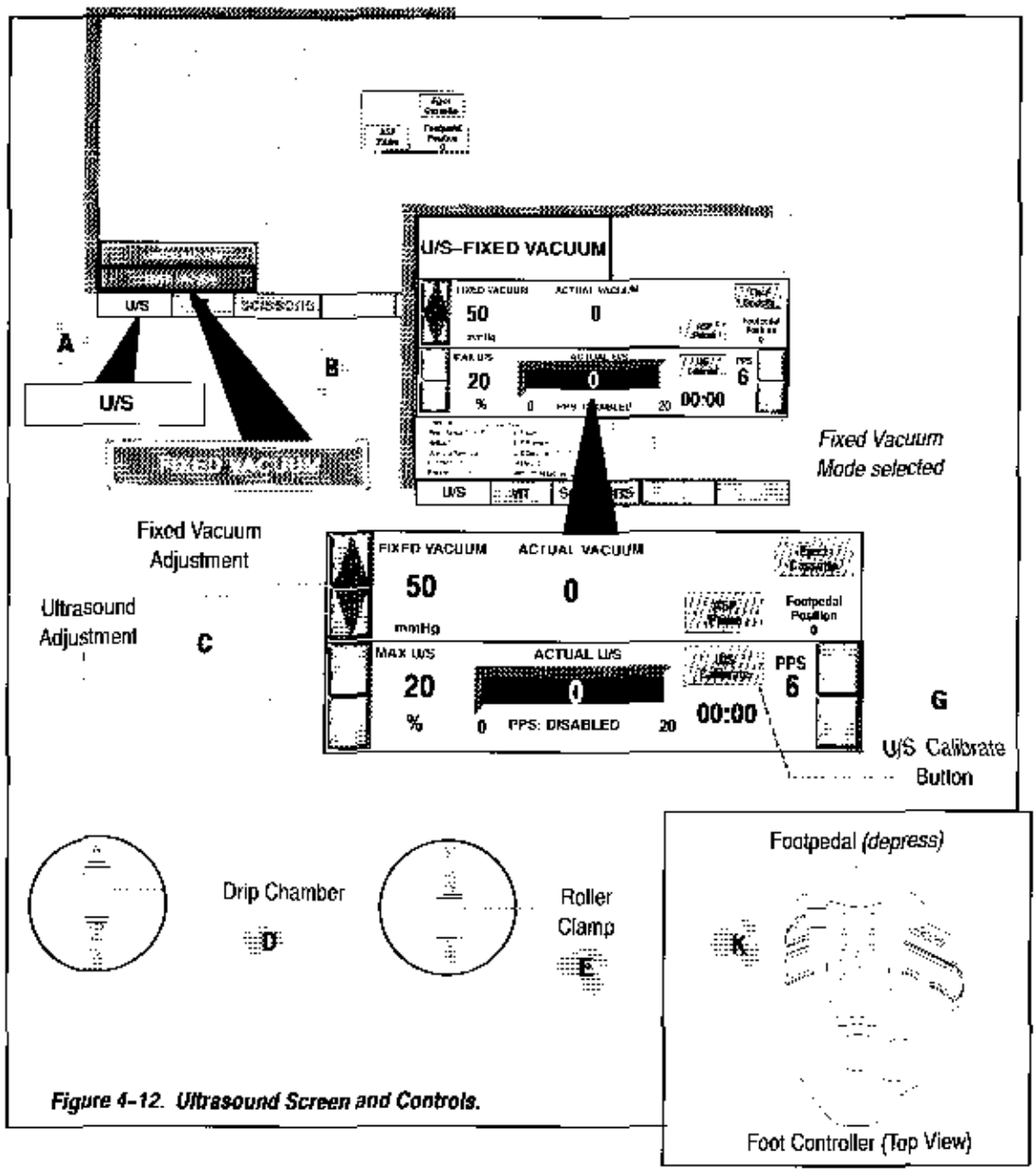


Figure 4–12. Ultrasound Screen and Controls.

4.8. Coagulation Module

Bipolar coagulation is accomplished with the ***Storz Millennium™ Microsurgical System's*** *Coagulation Module*. Bipolar forceps, or pencil handpieces are used as electrodes.

Coagulation is selectable at all times, and available when displayed on the screen. Coagulation power may be adjusted from 0% to 100% of the output power (above) using the up/down arrow keys as follows:

- Between 0% and 20%, changes are in increments of 1% with each key press.
- Between 20% and 40%, changes are in increments of 2% with each key press.
- Between 40% and 100%, changes are in increments of 5% with each key press.

Coagulation modes available are:

- *Fixed coagulation mode* – Provides an adjustable output between 0% and 100% as described previously. Power levels are set via spin button control. Fixed coagulation is actuated by displaying it on the screen and pressing the blue button on the Foot Controller. It remains activated as long as the button remains depressed.

WARNING:
Check the coagulation power level when changing between extraocular and intraocular cauterization.

WARNING:
Use only bipolar handpieces and cables designated by Storz Instrument Company for use with this system.

- *Linear coagulation mode* – Provides an adjustable output between 0% and 100% as described previously. Power levels are set via spin button control. Linear coagulation is actuated by depressing the center footpedal. The footpedal is programmed to provide linear control as a function of angular footpedal displacement

WARNING:
Assure the handpiece and accessories are sterilized before use as specified.

Fixed Coagulation Set-up And Use

A. Connect the desired bipolar forceps or pencil *(see figure 4—13)* to its cable. The use of an adapter may be necessary.

B. Connect the bipolar cable to the coagulation module electrical connector.

C. Press the **TOOLS** selection tab at the bottom of the screen. The tabs will expand upward.

D. Select **Fixed Coagulation** and the fixed coagulation interface frame is displayed.

E. Use the spin buttons to adjust the percent of coagulation power desired.

F. The fixed coagulation function is activated by pressing the **blue foot controller switch**. When the switch is released, the function will deactivate.

G. A tone will signify bipolar coagulation operation.

NOTE:
See chapter 5 for cleaning and sterilization requirements when surgery is completed.

NOTE:
See chapter 3 page 3–8 for setting audio levels.

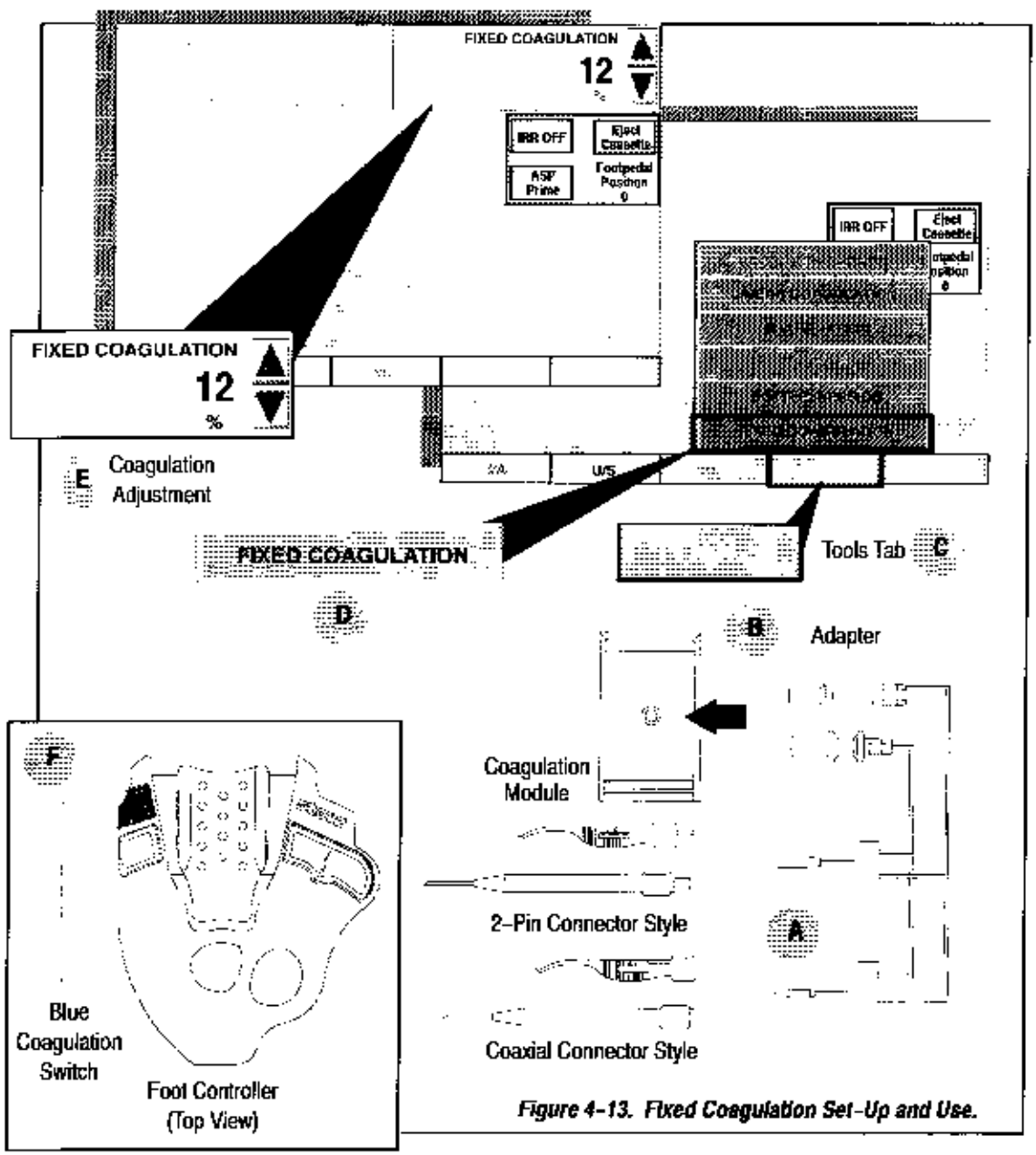


Figure 4-13. Fixed Coagulation Set-Up and Use.

Linear Coagulation Set-Up and Use

A. Connect the desired bipolar forceps or pencil *(see figure 4–14)* to its cable.

B. Connect the bipolar cable to the coagulation module electrical connector.

C. Press the **TOOLS** selection tab at the bottom of the screen. The tabs will expand upward.

D. Select **LINEAR COAGULATION** and the linear coagulation interface frame is displayed.

E. Use the spin buttons to adjust the **MAX COAGULATION** power desired.

F. The linear coagulation function is actuated by the center foot pedal. The **ACTUAL COAGULATION** progress bar will display the amount of coagulation power being used in relation to the maximum setting.

G. A tone will signify bipolar coagulation operation.

WARNING:
Assure the handpiece and accessories are sterilized before use as specified.

NOTE:
See chapter 3 page 3–8 for setting audio levels.

NOTE:
See chapter 5 for cleaning and sterilization requirements when surgery is completed.

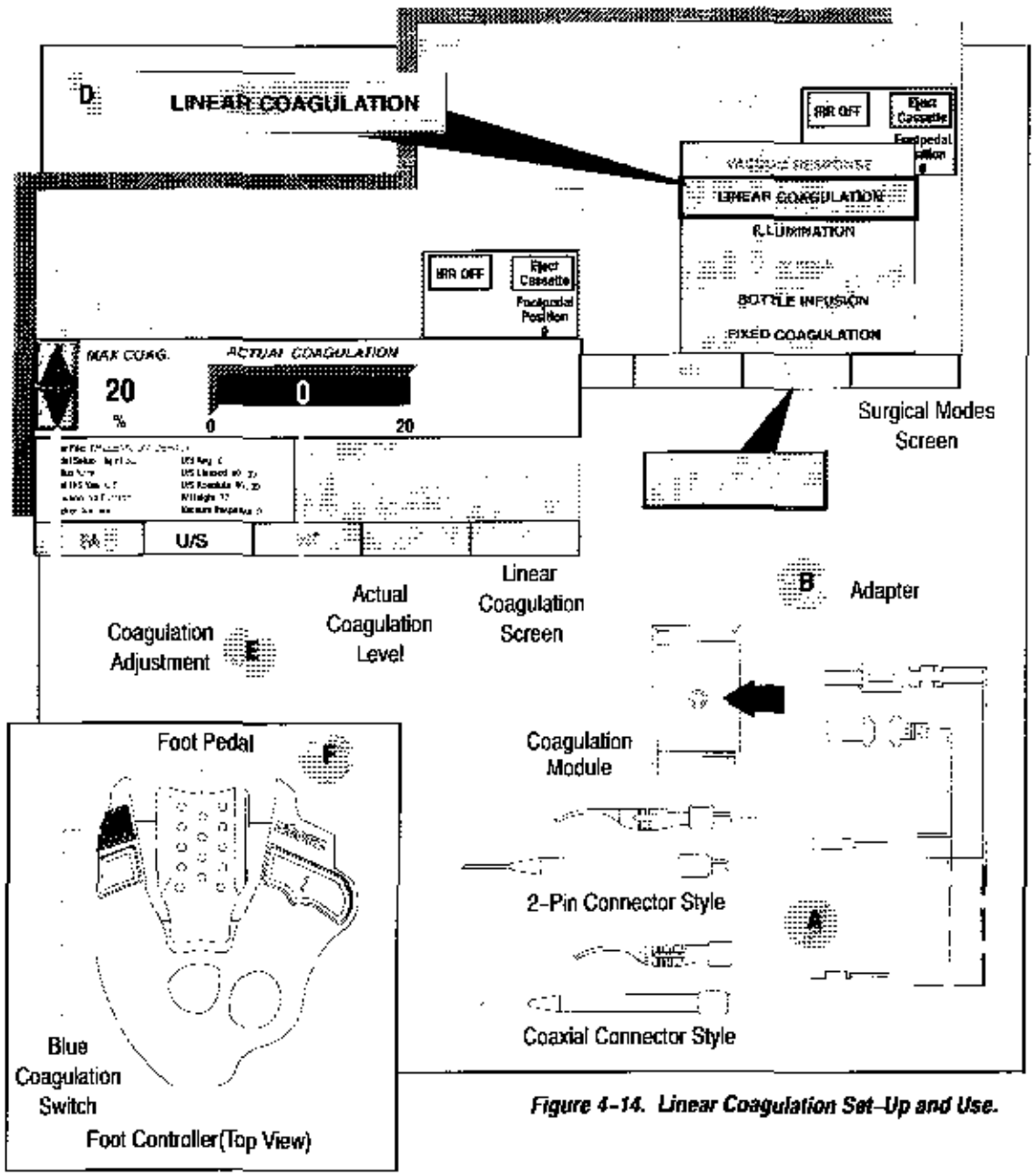


Figure 4-14. Linear Coagulation Set-Up and Use.

4.9. Illumination Module

Fiber optic illumination for intraocular viewing is accomplished with the *Storz Millennium™ Microsurgical System's Illumination Module*. Two ACMI compatible ports provide simultaneous operation with independent control. Each source may be independently adjusted for intensity. The light transmitted to the patient will have a spectral content between 400 nm and 750 nm, and an average luminous output of 60 candela per square millimeter.

WARNING:
Care should be taken to avoid concentrating the output of the illumination module on a small area of the retina for unnecessarily prolonged periods of time due to the potential for phototoxicity.

Illumination Setup and Use

A. Connect the fiber optic endoilluminator to the desired ACMI port on the illumination module *(see figure 4–15)*.

B. Press the **TOOLS** selection tab at the bottom of the screen. The tabs will expand upward.

C. Select **ILLUMINATION** and the illumination interface frame is displayed.

D. Choose either **LAMP 1** (upper lamp) or **LAMP 2** (lower lamp). The button will indicate **ON**.

E. Allow 30 seconds for lamp to reach full output, then use the slide control to adjust the intensity. Never turn the illumination on and off rapidly (see note).

Should the light source fail during use, the operator must switch the fiber optic endoilluminator to the other lamp ACMI port. The burned out lamp should then be replaced before the next surgery.

NOTE: *To preserve the lamp integrity, Illumination Modules are shipped with the lamps packaged separately.*

NOTE: *Installation and replacement of the lamps is discussed in paragraph 7.4 on page 7–10.*

NOTE: *To prolong lamp life, turn off the illumination only when it will be unused for more than one hour.*

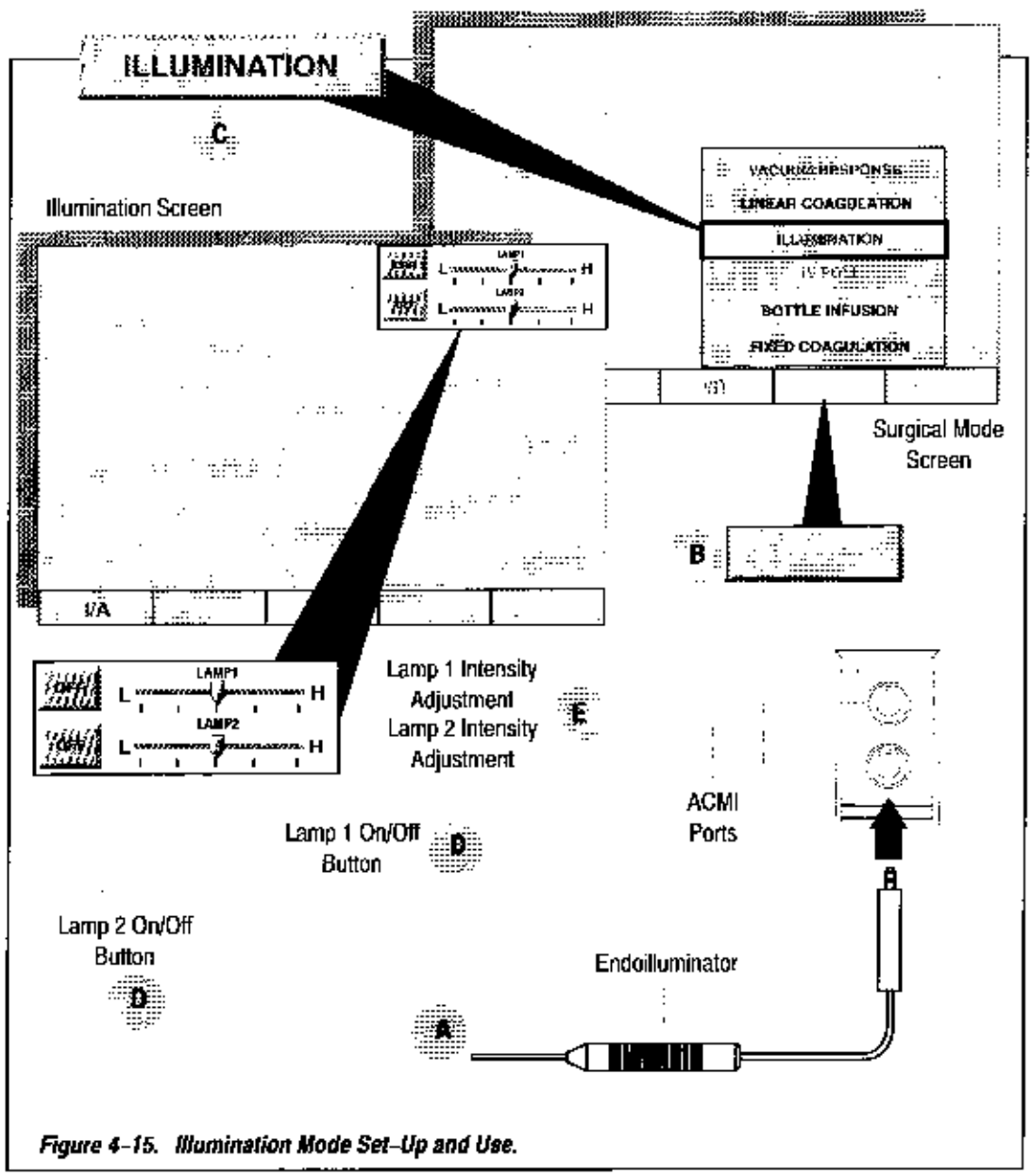
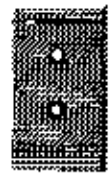


Figure 4–15. Illumination Mode Set–Up and Use.

4.10. Scissors/Air Module



Scissors/Forceps

Scissors/Forceps portion of the ***Storz Millennium*** ™ ***Microsurgical System's*** *Scissors/Air Module* supports operation of an electrically driven handpiece. Actuation parameters are set via the touch screen, and actuation is controlled from the foot controller. Two types of handpieces are available: the Millennium™ Vertical Scissors and the Millennium ™ Proportional Handpiece. The Millennium ™ Vertical Handpiece will accept a vertical scissors tip, and the Proportional Handpiece is compatible with the Storz ***ErgoTec*** ™ instrument tips.

Scissors/Forceps Operation

Four operational modes are available when **SCISSORS** is selected from the ***Posterior*** menu.

- **Single Cut Mode.** The instrument tip is closed for entering the eye when the left rocker switch is depressed. The right rocker switch actuates the tip in a single cut.
- **Fixed Cut Mode.** The maximum cutting speed may be set from 30 to 300 cuts per minute in 30 cut per minute increments utilizing the up/down spin buttons (or 1 cut per minute using the numeric keypad). The right rocker switch actuates the tip at a fixed cut rate.
- **Linear Cut Rate Mode.** The maximum cutting speed may be set from 30 to 300 cuts per minute in 30 cut per minute increments utilizing the up/down spin buttons (or 1 cut per minute using the numeric keypad). The actual cut rate is varied as a function of the linear displacement of the foot pedal in the pitch direction. The cutter may

be held closed by moving the foot pedal in the inward yaw direction.

- **Proportional mode**. The left rocker switch opens the tip and the right rocker switch closes the tip. The tip stays in the open or closed position it is in when the switch is released. The switches may be activated incrementally in partially open positions.

Scissors Set–up

Refer to ***figure 4–16*** for the following steps.

A. Connect the appropriate microscissors or forceps tip to the handpiece.

B. Connect the electrical connector of the handpiece to the Scissors connector on the module.

C. Remove the protective guard by pulling it away from the tip toward the handle.

D. Press the **SCISSORS** tab to expand the selections. Then select the desired mode (single cut, fixed cut, linear cut, or proportional). Use the spin buttons to adjust the cut rate

E. Depress the proper control to test and verify that the blades open and close correctly for the selected mode.

F. Close instrument tip when entering the eye.

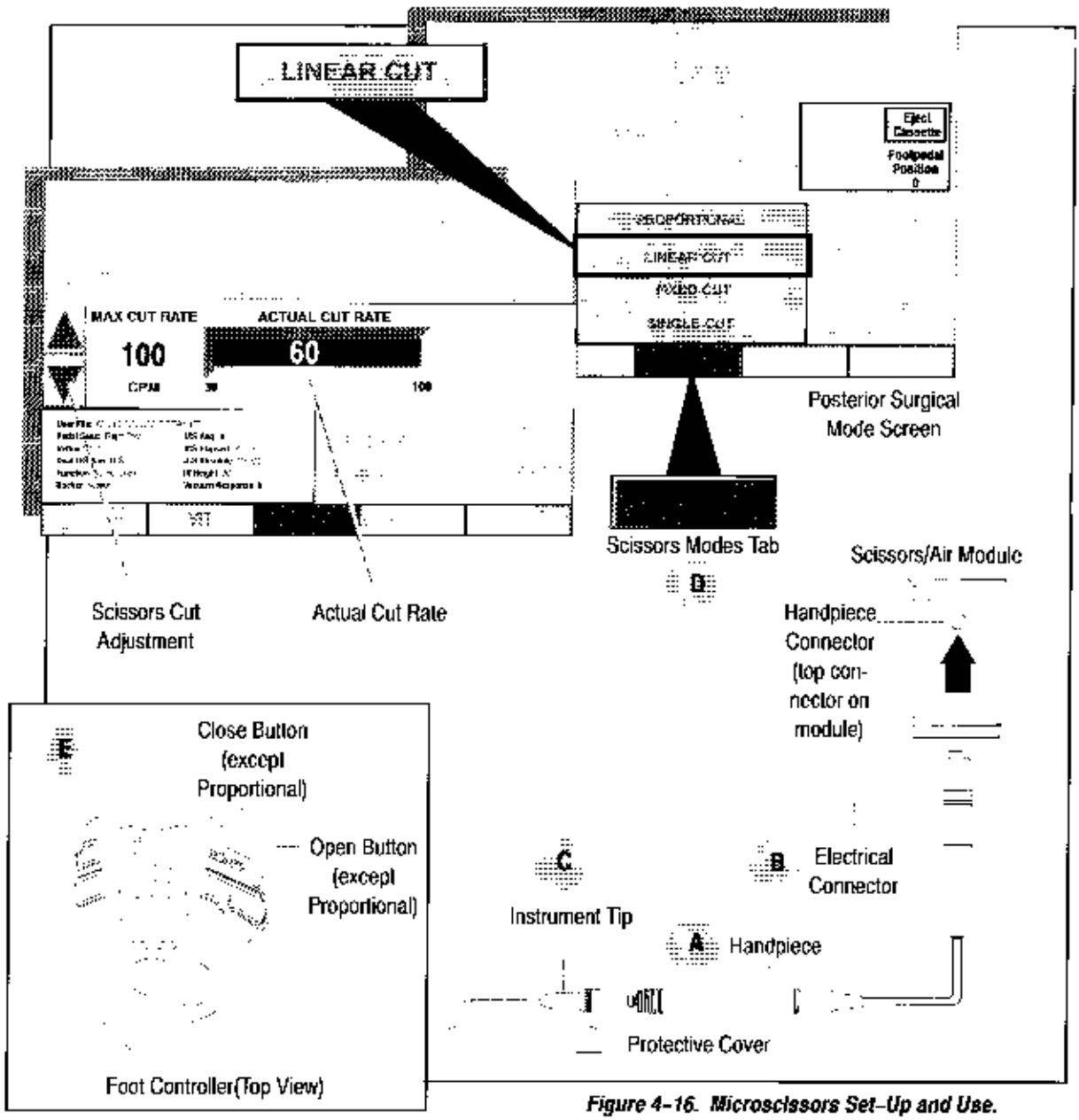


Figure 4-16. Microscissors Set-Up and Use.

Air/Fluid Exchange

The Air/Fluid Exchange portion of the ***Storz Millennium*** ™ ***Microsurgical System's*** *Scissors/Air Module* supports the operation of a single air port driven from a pneumatic pump located within the module. The air pressure from the pump may be adjusted from 10 to 100 mmHg in 1 mmHg increments. This feature may be used in the posterior mode for air/fluid exchange, or in the anterior mode to pressurize the infusion bottle. Air is filtered through a disposable hydrophilic filter.

Air/Fluid Exchange Operation

The ***Air/Fluid Exchange*** mode is a posterior feature which provides the surgeon with the ability to instill a preset air pressure into the eye for air/fluid exchange. It supports pressures up to 100 mmHg at flow rates up to 3.5 standard cubic feet (99 liter) per hour.

Air/Fluid Exchange Set–up

Refer to ***figure 4–17*** *for the following steps.*

A. Close the roller clamp to the irrigation administration tube set. Spike and hang a bottle of balanced salt solution to the administration tube set.

B. Connect a three–way stopcock to one end of the irrigation line. Connect the irrigation administration set to the stopcock.

C. Connect the infusion cannula to the other end of the irrigation line.

D. Connect the unfiltered male Luer end of the air exchange line to the open port of the stopcock.

E. Connect the filtered end of the air exchange line to the air connector on the module.

F. Press the **TOOLS** selection tab at the bottom of the screen. The tabs will expand upward.

G. Press the **AIR FLUID EXCHANGE** tab, and the air/fluid exchange interface frame is displayed.

H. Using the spin buttons adjust the pressure.

I. Press the **OFF** button to turn on.

J. Squeeze and release the drip chamber until 1/2 filled with solution.

K. Turn the valve of the stopcock to stop the flow of irrigating solution and start the flow of air.

NOTE: *If setup is done at the beginning of the procedure, ensure the irrigation administration set, irrigation line, and unfiltered end of the air exchange line are connected to a stopcock.*

NOTE: *Use the stopcock to switch between irrigating solution and air exchange.*

NOTE: *Once Air Fluid Exchange is turned ON, it will continue to operate even when the tool is removed from the display.*

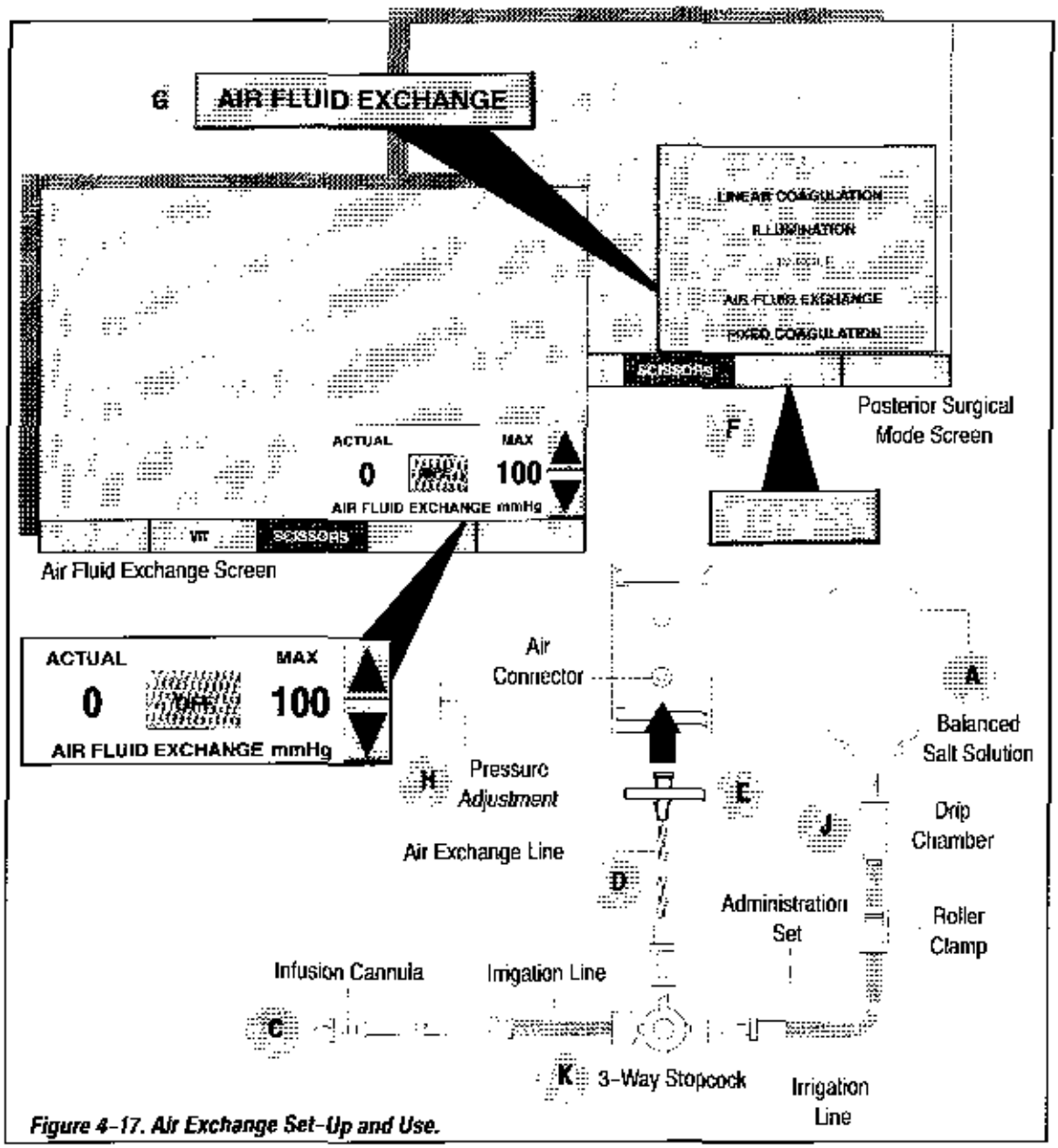


Figure 4-17. Air Exchange Set-Up and Use.

Bottle Infusion Operation

The ***Bottle Infusion*** mode is an anterior feature which provides the surgeon the ability to instill a preset air pressure to pressurize an IV bottle for intraocular pressure (IOP) control. If this feature is used to pressurize a fluid supply, the fluid level in the drip chamber must first be set at the patient eye level. The pressure may then be increased by adjusting the bottle infusion level rather than adjusting the bottle height.

Bottle Infusion Set–up

Refer to ***figure 4–18*** for the following steps:

A. Connect the filtered end of the IOP Control Tubing Set to the air connector on the module.

B. Connect the green line of the IOP Control Tubing Set to the green irrigation line of the I/A tubing set.

C. Close the roller clamp. Spike and hang a bottle of balanced salt solution to the IOP Control Tubing Set. Set the bottle to the desired height.

D. Press the **TOOLS** selection tab and then select **BOTTLE INFUSION**.

E. Use the up and down arrows to select the desired pressure.

F. Press the **OFF** button to turn on bottle infusion.

NOTE: *Hang the bottle so that the drip chamber is at the patient eye level.*

NOTE: *Once Bottle Infusion is turned ON, it will continue to operate even when the tool is removed from the display.*

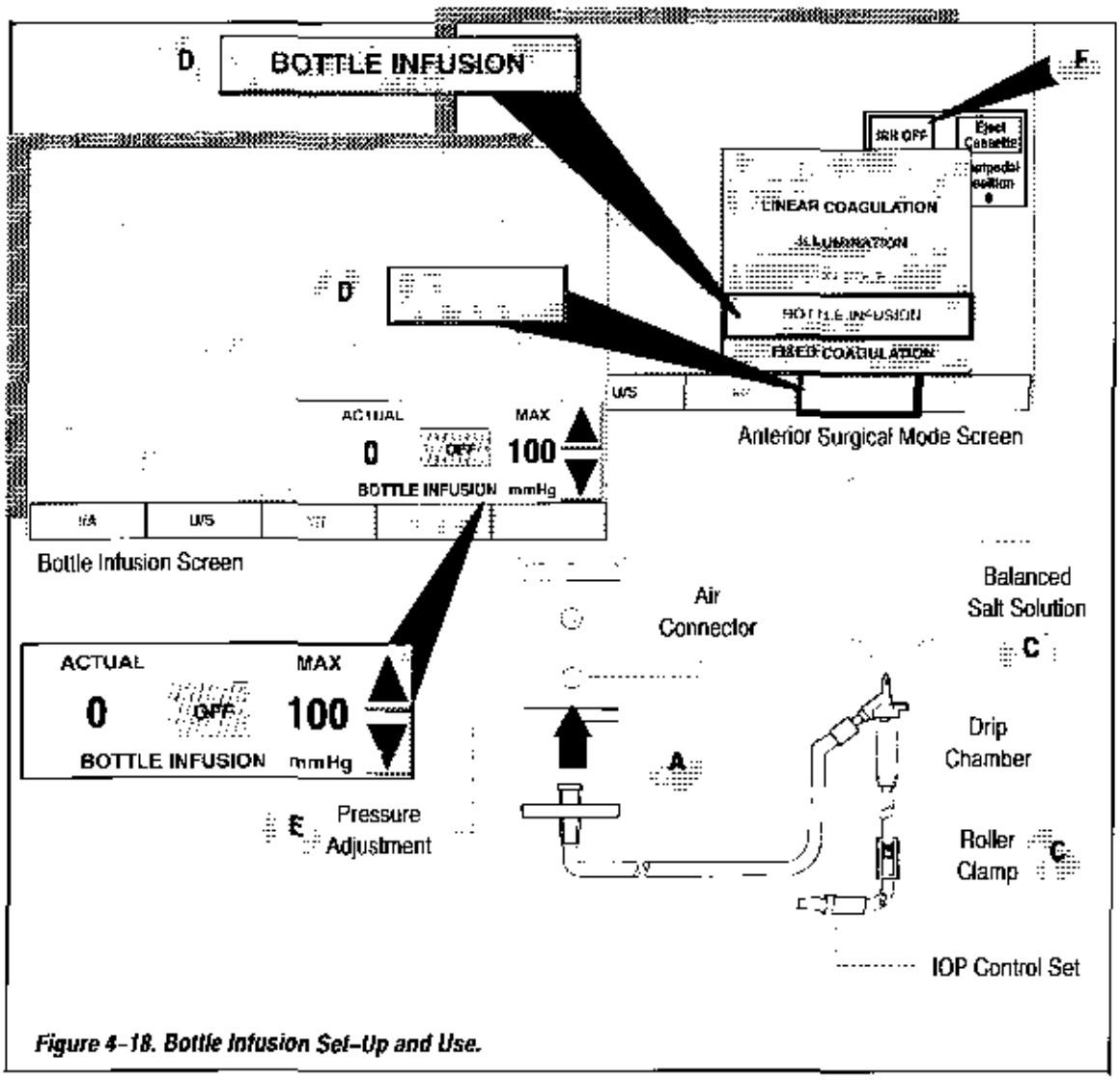


Figure 4–18. Bottle Infusion Set–Up and Use.

4.11. Viscous Fluid System Module

The *Storz Millennium™ Microsurgical System's Viscous Fluid Module* provides the capability to generate the required injection pressures and aspiration vacuums for injecting or aspirating viscous fluids into and out of the eye during posterior surgery. All other posterior system function except phacofragmentation may be operated simultaneously or in conjunction with this module.

When used in the injection mode, the *Viscous Fluid Module* will deliver up to 70 psi (482.6 KPa, 4.8 bar) of pneumatic pressure to the disposable tube set. The system can inject up to 5 cc of 1000 to 5000 centistoke silicone oil @ 32°C in less than six minutes. One tool and one operation mode are available:

Top View

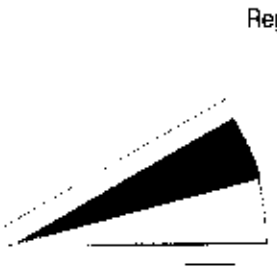
- *Fixed Fluid Injection Tool:* Control is via the rocker switch on the foot controller, or via a control button on the touch screen. The output will remain active until turned off by the rocker switch or touchscreen button. The pressure level is set using the spin buttons on the touch screen. When in fixed injection mode, the system allows simultaneous operation of venturi or scroll aspiration while injecting a viscous fluid.

- *Linear Fluid Injection Mode:* Control of linear fluid injection is via the center footpedal. The injection pressure increases proportional to footpedal travel from the minimum programmed setting to the maximum programmed setting. The minimum

and maximum pressure levels are set using the touch screen. Since the center footpedal is used for linear injection, other linear functions are not available.

When used in the aspiration mode, the *Viscons Fluid Module* will provide vacuums between 1 to 600 mmHg in 10 mmHg increments. The system can aspirate 5 cc of 5000 centistoke silicone oil @ 32°C in less than forty–five minutes. Two modes of operation are available:

- *Fixed Fluid Aspiration Mode:* Aspiration is activated when the center footpedal is depressed into region 1 and remains active until the footpedal is released. The vacuum level is set using the spin buttons on the touch screen, or using the foot controller rocker switch if programmed to do so.



Footpedal Activation Settings
See page 2-12.

- *Linear Fluid Aspiration Mode:* Control of aspiration is via the center footpedal in region 1. The aspiration vacuum increases proportional to footpedal travel from the minimum programmed setting to the maximum programmed setting. The minimum and maximum vacuum levels are set using the touch screen.

Viscous Fluid System Setup and Use

A. Press the **TOOLS** selection tab at the bottom of the screen. The tabs will expand upward *(see figure 4–19)*.

B. Select **Viscous Fluid** and the viscous fluid tabs are displayed.

Viscous Fluid Injection

C. Choose the injection function.

D. Set the pressure level desired.

E. Connect the locking air connector on the tubing set to the viscous fluid module.

F. With the syringe capped, pour the fluid into the syringe barrel at a 45° angle to prevent air bubbles from forming within the fluid.

G. Place the black piston into the end of the barrel just far enough to allow a connection to the coupler.

H. Connect the syringe to the coupler and twist to lock.

I. Slowly turn the syringe upward so that the tip points toward the ceiling, allowing any air to move to the tip in one cohesive bubble.

J. While holding the syringe in the upright position, uncap the syringe and attach the 19 ga. cannula.

K. Momentarily activate the system to evacuate all air from the syringe, and a bead of fluid form on the tip of the cannula.

L. The system is ready for use.

Viscous Fluid Aspiration

A. Press the **TOOLS** selection tab at the bottom of the screen. The tabs will expand upward *(see figure 4–19)*.

B. Select **Viscous Fluid** and the viscous fluid tabs are displayed.

C. Choose the desired aspiration function.

D. Set the vacuum level desired.

E. Connect the locking air connector on the tubing set to the viscous fluid module.

F. Remove the cap from the syringe.

G. Place the black piston into the end of the barrel and push all the way down to the tip of syringe.

H. Connect the syringe to the coupler and twist to lock.

J. While holding the syringe in the upright position, attach the 19 ga. cannula.

K. The system is ready for use.

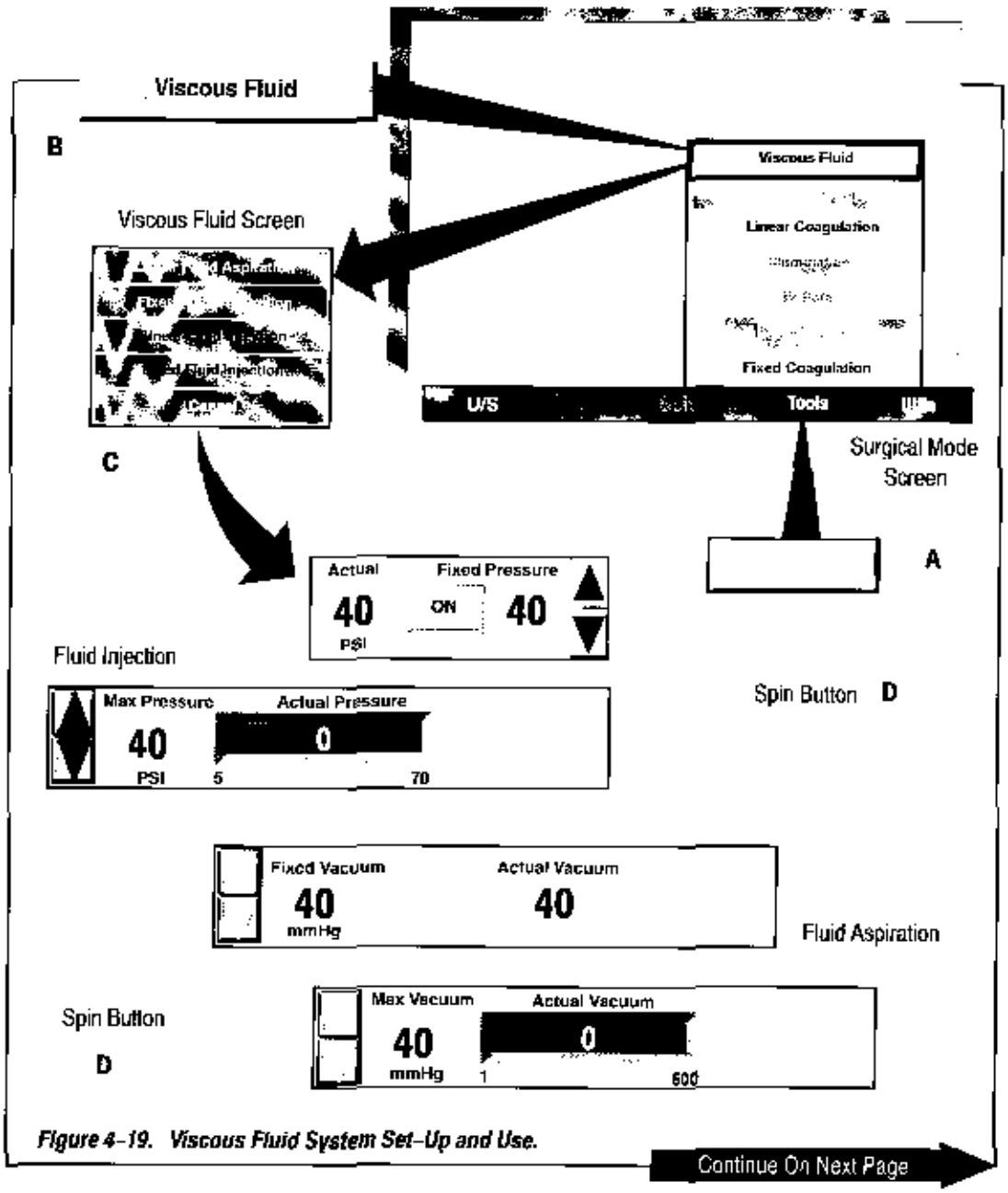


Figure 4–19. Viscous Fluid System Set–Up and Use.

Continue On Next Page

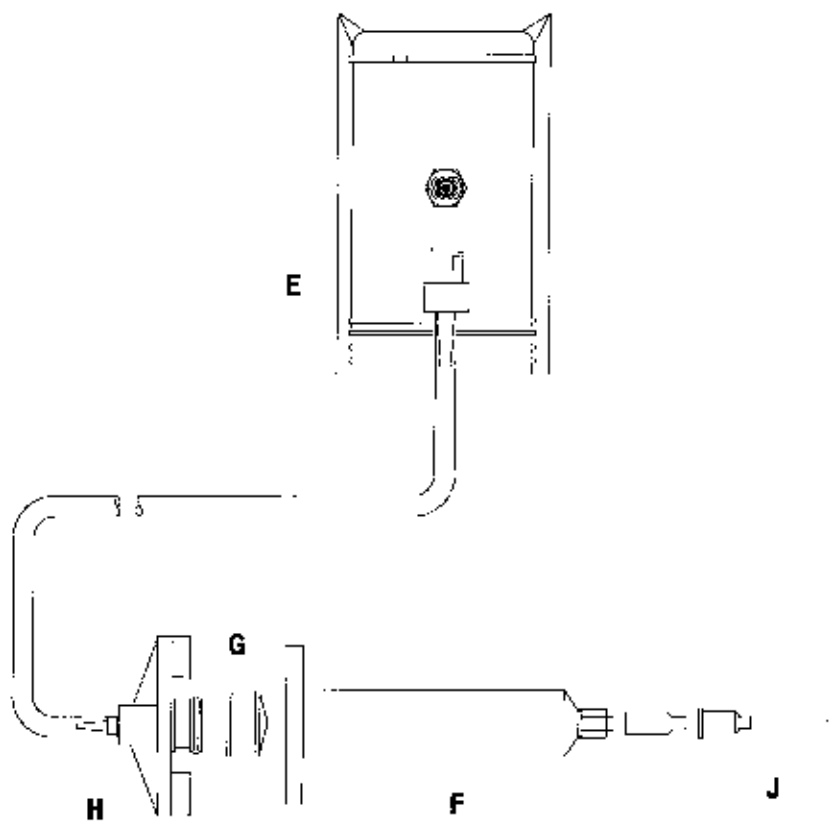


Figure 4–19. Viscous Fluid System Set–Up and Use. (continued)

Chapter 5

Cleaning and Sterilization Requirements

Chapter Objective: This chapter gives you instructions for cleaning the computer unit, base unit and cart, and cleaning and sterilization of the reusable coagulation accessories, the vertical scissors and proportional handpieces, the irrigation and irrigation/aspiration handpieces, the phacoemulsification handpiece, and the phacofragmentation handpiece.

5.1. Computer Unit, Base Unit and Cart.

WARNING:
Disconnect AC power before cleaning the cabinet.

CAUTION:
To preserve the cabinet finish, avoid the use of abrasive cleaners. If possible, clean spots before they dry.

The following products were tested and can be used on all external surfaces of the ***Storz Millennium ™ Microsurgical System***. Use of any substance not listed is at the user's responsibility.

- *Isopropyl Alcohol (70%)*
- *Mild Soap and Water*

Wipe the area to be cleaned using a soft cloth moistened with cleaning solution. Avoid applying any cleaner directly to the display (apply to cloth sparingly). Avoid excessive quantities of cleaning solution around the electrical, pneumatic, and illumination ports. Remove all traces of the cleaning solution with a cloth dampened with clean water. The surfaces should then be dried with a lint–free cloth.

5.2. Bipolar Coagulation Accessories.

The bipolar coagulation forceps, eraser, and reusable cord should be inspected before each use for signs of misalignment, pitting, contamination (blood, tissue, etc.), or other damage. Blood, saline, tissue, and other contamination on the tips may be removed by gently scraping with a scalpel blade. If the forceps are dropped and seriously misaligned, or if deep pits or scores appear on the tips after long use, the forceps may be returned to Storz Instrument Co. for repair, refinishing, or repotting of the insulating base. With the exception of flash and gas methods, the items may be wrapped in a surgical towel, CSR wrap, or equivalent.

Wipe the forceps using a soft cloth moistened with a mild soap water solution. Avoid excessive quantities of solution around the electrical connector. Remove all traces of the solution with a cloth dampened with clean water. The surfaces should then be dried with a lint–free cloth.

The forceps may be sterilized as follows:

- *Standard Gravity Steam Sterilization: Wrapped for* 30 minutes at 121° C (250° F).
- *Flash Sterilization: Unwrapped but covered for* 10 minutes at 132° C (270° F).

WARNING:
The coagulation accessories should not be sterilized using a cold soaking solution.

NOTE:
Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.

WARNING:
Allow 20 minutes for the handpiece to cool after sterilization before it is used.

- *High Vacuum (Pre- vacuum) Sterilization: Wrapped for* 3 minutes at 134° C (274.° F).

The reusable cables may be sterilized as follows:

- *Ethylene- oxide Method:* Using Oxyfume 2000 (10:90) gas for 2 hours. Gas concentration should be set at 600 mg/L ethylene oxide, and a chamber temperature of 55° C (125° F). Aeration following exposure shall be 18 hours at 50° C (122° F).
- *Standard Gravity Steam Sterilization: Wrapped for* 30 minutes at 132° C (270° F).
- *High Vacuum (Pre–vacuum) Sterilization: Wrapped for* 4 minutes at 132° C, –0° C/+3° C (270° F).

5.3. Irrigation Handpiece and Irrigation/Aspiration Handpiece.

WARNING:
Do not cold sterilize the instrument. The sterilizing solution may not be flushed out prior to surgery and could be flushed into the eye, resulting in serious eye injury.

The handpiece must be flushed clean and autoclaved before it is placed into service the first time, before initial use each day, and between each use in accordance with the following instructions. The ***Storz Millennium™ Microsurgical System*** may be used to initially flush debris (prior to cleaning) from the aspiration handpiece before it is disconnected by pressing ***ASP Prime***.

Handpiece Cleaning Instructions.

A. Disconnect tubing and remove irrigation sleeve.

B. Cleaning of the irrigation/aspiration Luer adaptor shall be performed prior to cleaning of lumens. Remove the adaptor from the handpiece.

C. Rinse the Luer adaptor using distilled water for ten seconds. Attention must be given to ensure the passage of

distilled water through each lumen and adequate cleaning of Luer barbs.

D. Place the end of the syringe into a beaker of warm *(30° C to 40° C — 85° F to 105° F)* distilled or deionized water, and fill the syringe to the 50cc (ml) mark.

E. Connect the end of the syringe to the center stopcock fitting *(see figure 5–1)*.

F. Rotate the stopcock lever to allow fluid flow to the male Luer fitting.

G. Reattach the Luer adapter to the handpiece. Ensure irrigation tube (green stripe) is inserted onto the larger irrigation fitting of the handpiece.

H. Connect the stopcock male Luer fitting to the handpiece irrigation fitting.

I. Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. **DO NOT DRAW FLUSHING FLUID BACK THROUGH THE HANDPIECE.** Disconnect the syringe.

J. Repeat steps D through I at least three times.

K. Fill the syringe with air, reattach to stopcock, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.

L. Repeat step K at least three times.

M. If an I/A probe is being cleaned, continue with the following steps.

N. Refill the syringe to the 50cc (ml) mark with warm *(30° C to 40° C — 85° F to 105° F)* distilled or deionized water.

O. Connect the syringe to the center stopcock fitting.

P. Rotate the stopcock lever to allow fluid flow to the female Luer fitting.

Q. Connect the stopcock female Luer fitting to the handpiece aspiration fitting.

NOTE:
Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.

CAUTION:
Use only warm (30° C to 40° C — 85° F to 105° F) distilled or deionized water to flush the handpiece.

R. Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. **DO NOT DRAW FLUSHING FLUID BACK THROUGH THE HANDPIECE.** Disconnect the syringe.

S. Repeat steps N through R at least three times.

T. Fill the syringe with air, reattach to stopcock, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.

U. Repeat step T at least three times.

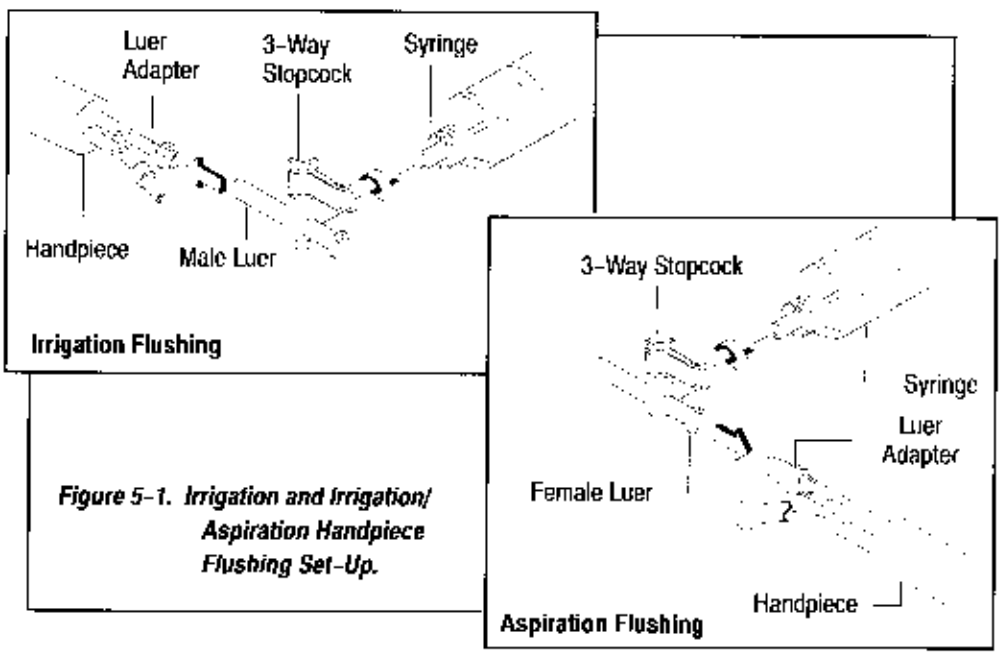


Figure 5-1. Irrigation and Irrigation/ Aspiration Handpiece Flushing Set-Up.

Irrigation and I/A Handpiece Sterilization.

The handpiece and any reusable accessories or tubing must be autoclaved before any item is used. Silicone tubing must be removed from all instruments prior to sterilization in order to prevent moisture build-up at the contact areas. The hand

piece may be wrapped in a surgical wrap. With the exception of flash sterilization, the items may be wrapped in a surgical towel, CSR wrap, or equivalent. The minimum requirements for sterilization are:

- *Standard Gravity Steam Sterilization: Wrapped for* 30 minutes at 121 C (250° F).
- *Flash Sterilization: Unwrapped but covered for* 10 minutes at 132 C (270° F).
- *High Vacuum (Pre vacuum) Sterilization: Wrapped for* 3 minutes at 134° C (274.° F).

WARNING:
Allow 20 minutes for the handpiece to cool after sterilization before it is used.

5.4. Phacoemulsification Handpiece

NOTE:
Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.

The ultrasound handpiece, reusable accessories, and cord should be inspected before each use for signs of contamination, or other damage. If the handpiece, its cord, or any reusable accessory show signs of damage or cracked insulation, it should not be used. The handpiece must be flushed clean and autoclaved before it is placed into service the first time, before initial use each day, and after each use in accordance with the following instructions:

Handpiece Cleaning Instructions

Storz recommends the use of the Storz *Universal Maintenance Kit CX7120* in the following instructions. The irrigation sleeve, needle, and tubing must be removed from the handpiece before beginning.

A. Remove the silicone irrigation sleeve and the needle. Remove any tubing from the rear of the handpiece. See figure 5–2.

B. Wipe the handpiece using a soft cloth moistened with a mild soap water solution. Avoid excessive quantities of solution around the electrical connector. Remove all traces of the solution with a cloth dampened with clean

water. The surfaces should then be dried with a lint–free cloth.

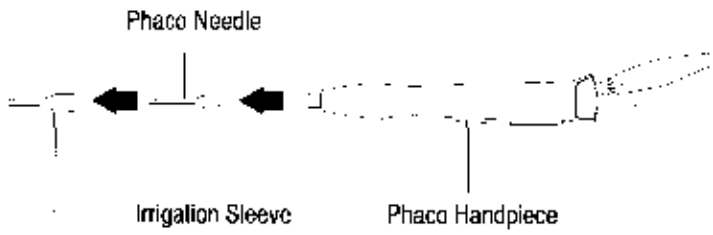


Figure 5–2. Needle and Irrigation Sleeve Attachment

NOTE: *For users in the United Kingdom, please refer to page 5–18 for special cleaning and sterilization instructions before proceeding.*

C. Flush the irrigation lumen as follows (see figure 5–3):

1. Place the end of the syringe into a container of warm *(30° C to 40° C – 85° F to 105° F)* distilled or deionized water, and fill the syringe to the 50cc (ml) mark.
2. Connect the end of the syringe to the center stop cock fitting.
3. Rotate the stopcock lever to allow fluid flow to the male Luer fitting.
4. Connect the stopcock male Luer fitting to the handpiece irrigation fitting.
5. Push on the syringe plunger to force fluid through the handpiece into another container for proper disposal. **DO NOT DRAW FLUSHING FLUID BACK THROUGH THE HANDPIECE.** Disconnect the syringe.
6. Repeat steps 1 through 5 at least three times.

7. Fill the syringe with air, reattach to stopcock, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.
8. Repeat step 7 at least three times.

D. Flush the aspiration lumen as follows (see figure 5–3):

1. From the rear of the handpiece, insert aspiration brush (provided in the Storz *Universal Maintenance Kit*) into the aspiration fitting.
2. Push the brush bristles through the handpiece aspiration lumen, then pull the brush back out. Clean the brush after each use and sterilize at the end of each day according to the handpiece maintenance instructions.
3. Refill the syringe to the 50cc (ml) mark with warm *(30° C to 40° C – 85° F to 105° F)* distilled or deionized water.
4. Connect the syringe to the center stopcock fitting.
5. Rotate the stopcock lever to allow fluid flow to the female Luer fitting.
6. Connect the stopcock female Luer fitting to the handpiece aspiration fitting.
7. Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. **DO NOT DRAW FLUSHING FLUID BACK THROUGH THE HANDPIECE.** Disconnect the syringe.
8. Repeat steps 3 through 7 at least three times.
9. Fill the syringe with air, reattach to stopcock, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.
10. Repeat step 9 at least three times.

CAUTION:
Use only warm (30° C to 40° C – 85° F to 105° F) distilled or deionized water to flush the handpiece.

NOTE: *You may use filtered compressed medical grade air (medical grade nitrogen) to blow out the tubing. If so, the pressure should not exceed 29 psi (200 kPa, 2 bar).*

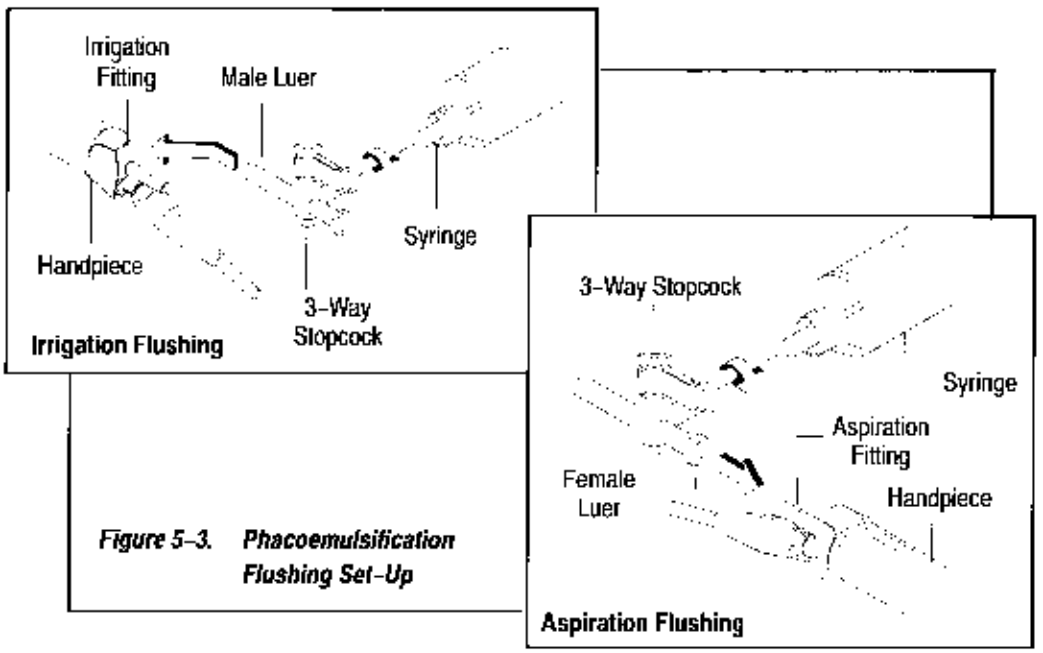


Figure 5–3. Phacoemulsification Flushing Set-Up

Phacoemulsification Handpiece Sterilization

The handpiece, needle and irrigation sleeve must be sterilized before use. The handpiece may be wrapped in a surgical wrap (except in flash sterilization). With the exception of flash sterilization, the items may be wrapped in a surgical towel, CSR wrap, or equivalent. The minimum requirements for sterilization are:

- *Standard Gravity Steam Sterilization: Wrapped for* 30 minutes at 121° C (250° F).
- *Flash Sterilization: Unwrapped but covered for* 10 minutes at 132° C (270° F).
- *High Vacuum (Pre vacuum) Sterilization: Wrapped for* 3 minutes at 134° C (274.° F).

WARNING:
Do not cold sterilize the instrument. The sterilizing solution may not be flushed out prior to surgery and could be flushed into the eye, resulting in serious eye injury.

WARNING:
Allow 20 minutes for the handpiece to cool after sterilization before it is used.

CAUTION:
Before each use, the hand piece and power cord should be inspected for damage (e.g. nicks, crimps, dents, exposed wires, etc.). If the handpiece is damaged, it should be immediately removed from service.

NOTE:
Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.

5.5. Phacofragmentation Handpiece

NOTE:
Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.

The ultrasound handpiece, reusable accessories, and cord should be inspected before each use for signs of contamination, or other damage. If the handpiece, its cord, or any reusable accessory show signs of damage or cracked insulation, it should not be used. The handpiece must be flushed clean and autoclaved before it is placed into service the first time, before initial use each day, and between each use in accordance with the following instructions.

Handpiece Cleaning Instructions

CAUTION:
Use only warm (30° C to 40° C – 85° F to 105° F) distilled or deionized water to flush the handpiece.

Storz recommends the use of the Storz *Universal Maintenance Kit CX7120* in the following instructions. The needle and tubing must be removed from the handpiece before beginning.

A. Remove the needle. Remove any tubing from the rear of the handpiece.

B. Wipe the handpiece using a soft cloth moistened with a mild soap water solution. Avoid excessive quantities of solution around the electrical connector. Remove all traces of the solution with a cloth dampened with clean water. The surfaces should then be dried with a lint-free cloth.

NOTE: *For users in the United Kingdom, please refer to page 5–18 for special cleaning and sterilization instructions before proceeding.*

C. From the rear of the handpiece, insert aspiration brush (provided in the Storz *Universal Maintenance Kit*) into the aspiration fitting.

D. Push the brush bristles through the handpiece aspiration lumen, then pull the brush back out. Clean the brush after each use and sterilize at the end of each day according to the handpiece maintenance instructions.

E. Place the end of the syringe into a container of warm*(30° C to 40° C – 85° F to 105° F)* distilled or deionized water, and fill the syringe to the 50cc (ml) mark.

F. Connect the end of the syringe to the center stopcock fitting *(see figure 5–4)*.

G. Rotate the stopcock lever to allow fluid flow to the female Luer fitting.

H. Connect the stopcock female Luer fitting to the handpiece aspiration fitting.

I. Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. **DO NOT DRAW FLUSHING FLUID BACK THROUGH THE HANDPIECE**. Disconnect the syringe.

J. Repeat steps E through I at least three times.

K. Fill the syringe with air, reattach to stopcock, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.

L. Repeat step K at least three times.

WARNING:
Do not cold sterilize the instrument. The sterilizing solution may not be flushed out prior to surgery and could be flushed into the eye, resulting in serious eye injury.

NOTE: *You may use filtered compressed medical grade air (medical grade nitrogen) to blow out the tubing. If so, the pressure should not exceed 29 psi (200 kPa, 2 bar).*

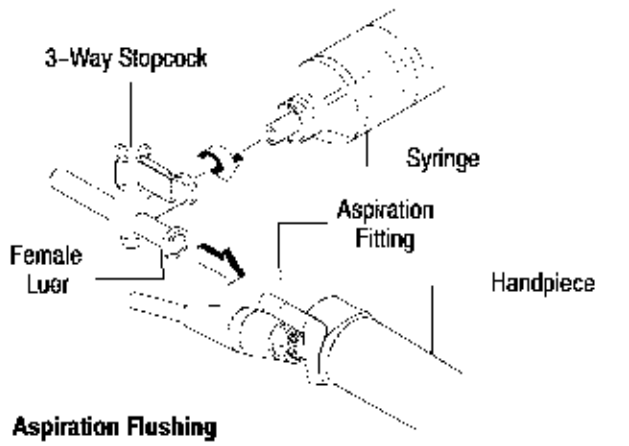


Figure 5–4. Phacofragmentation Flushing Set-Up.

Phacofragmentation Handpiece Sterilization

The handpiece and needle must be autoclaved before any use. The handpiece may be wrapped in a surgical wrap. With the exception of flash sterilization, the items may be wrapped in a surgical towel, CSR wrap, or equivalent. The minimum requirements for sterilization are:

- *Standard Gravity Steam Sterilization: Wrapped for* 30 minutes at 121° C (250° F).
- *Flash Sterilization: Unwrapped but covered for* 10 minutes at 132° C (270° F).
- *High Vacuum (Pre-vacuum) Sterilization: Wrapped for* 3 minutes at 134° C (274° F).

NOTE:
Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.

WARNING:
Allow 20 minutes for the handpiece to cool after sterilization before it is used.

5.6. *Microscissors Handpiece.*

NOTE:
Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.

CAUTION:
Use only warm (30° C to 40° C – 85° F to 105° F) distilled or deionized water to flush the handpiece.

WARNING:
Allow 20 minutes for the handpiece to cool after sterilization before it is used.

The microscissors handpiece, tips, and reusable cord should be inspected before each use for signs of misalignment, pitting, contamination, or other damage. Wipe the handpiece using a soft cloth moistened with a mild soap water solution. Avoid excessive quantities of solution around the electrical connector. Remove all traces of the solution with a cloth dampened with clean water. The surfaces should then be dried with a lint–free cloth. If deep pits or scores appear on the tips after long use, they should be discarded. If the handle or cord show signs of damage or cracked insulation, it should not be used.

Clean the instrument tip as described in step C through step K for ErgoTec ® Vitreoretinal Instruments paragraph 5.7. Sterilize using one of the three methods below. Store the tips as explained below.

With the exception of flash sterilization, the handpiece may be wrapped in a surgical towel, CSR wrap, or equivalent. The minimum requirements for sterilization are:

- *Standard Gravity Steam Sterilization: Wrapped for* 30 minutes at 121° C (250° F).
- *Flash Sterilization: Unwrapped but covered for* 10 minutes at 132° C (270° F).
- *High Vacuum (Pre–vacuum) Sterilization: Wrapped for* 3 minutes at 134° C (274.° F).

Tip Storage:

Replace the plastic tip guard by pressing the back end first onto the knurled portion of the tip and then carefully securing protective guard on to the tip.

5.7. ErgoTec™ Vitreoretinal Instruments.

A. Remove blood, saline, tissue, and other contaminants immediately by rinsing with warm *(30° C. to 40° C – 85° F. to 105° F)* distilled or deionized water. Tissue and other residue can be gently removed using an instrument cloth or sponge.

B. Wipe the handpiece using a soft cloth moistened with a mild soap water solution. Avoid excessive quantities of solution around the electrical connector. Remove all traces of the solution with a cloth dampened with clean water. The surfaces should then be dried with a lint–free cloth.

C. Rinse instrument thoroughly with warm distilled or deionized water.

D. Disassemble the instrument to flush out tip.

E. Fill a 60cc (ml) syringe with warm distilled or deionized water.

F. Secure the flush out adapter onto the Luer connector of the syringe and screw the instrument tip onto the flush out adaptor.

G. Force the water through the tip, DO NOT DRAW FLUID BACK INTO THE TIP. Repeat process as needed.

H. Disconnect the flush out adaptor.

I. Ultrasonically clean instrument tips for a minimum of 10 minutes after each use in warm distilled or deionized water to ensure thorough cleaning. Follow the manufacturer's instructions for proper use of your Ultrasonic Cleaner. Protective guard should be on tips during the ultrasound cycle.

J. Repeat steps E through H once.

NOTE:
Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.

CAUTION:
Use only warm (30° C to 40° C – 85° F to 105° F) distilled or deionized water to flush the handpiece.

K. Dry the instrument tips and handle thoroughly with forced air.

NOTE:
Specific instructions for cleaning and sterilization included with the handpiece or accessory take precedence over these instructions.

Sterilization:

Remove tip protector prior to sterilization. With the exception of flash sterilization, the items may be wrapped in a surgical towel, CSR wrap, or equivalent.

- *Standard Gravity Steam Sterilization: Wrapped for* 30 minutes at 121° C (250° F).
- *Flash Sterilization: Unwrapped but covered for* 10 minutes at 132° C (270° F).
- *High Vacuum (Pre-vacuum) Sterilization: Wrapped for* 3 minutes at 134° C (274° F).

Storage:

Replace the plastic tip guard by pressing the back end first onto the knurled portion of the tip and then carefully securing protective guard on to the tip.

WARNING:
Allow 20 minutes for the handpiece to cool after sterilization before it is used.

5.8. Special Instructions for United Kingdom Users.

Flush aspiration lumen (phaco & frag) as follows:

A. Place the end of the syringe into a beaker of warm *(30° C to 40° C)* distilled or deionized water, and fill the syringe to the 50cc (ml) mark.

B. Connect the end of the syringe to the center stopcock fitting.

C. Rotate the stopcock lever to allow fluid flow to the female Luer fitting.

D. Connect the stopcock female Luer fitting to the handpiece aspiration fitting.

E. Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. **DO NOT DRAW FLUSHING FLUID BACK THROUGH THE HANDPIECE.** Disconnect the syringe.

F. Repeat steps A through E at least three times.

G. Prepare a neutral pH detergent solution using warm distilled or deionized water, per the detergent manufacturer's labeling instructions.

H. Immerse aspiration brush (part of Storz *Universal Maintenance Kit)* into the detergent solution sufficiently to cover all of the brush bristles.

I. From the rear of the handpiece, insert aspiration brush into the aspiration fitting.

J. Push the brush bristles through the handpiece aspiration lumen several times. Care must be taken not to create an aerosol effect by pushing the bristles past the end of the handpiece. Then pull the brush back out. Thoroughly clean the brush after each use and sterilize at the end of

each day according to CX7120 handpiece maintenance instructions.

K. Rinse both ends of the handpiece aspiration lumen. Holding the handpiece downward at a 15° angle, and rinse the aspiration fitting with warm *(30° C to 40° C)* distilled or deionized water. Repeat this process for the front of the handpiece.

L. Wipe each end of the handpiece with clean gauze to remove any deposited protein material.

M. Refill the syringe with 50cc (ml) of warm distilled or deionized water (see figure 5–5 on page 5–19).

N. Connect the end of the syringe to the center stopcock fitting.

O. Rotate the stopcock lever to allow fluid flow to the female Luer fitting.

P. Connect the stopcock female Luer fitting to the handpiece aspiration fitting.

Q. Push on the syringe plunger to force fluid through the handpiece into another beaker for proper disposal. DO NOT DRAW FLUSHING FLUID BACK THROUGH THE HANDPIECE. Disconnect the syringe.

R. Repeat steps M through Q at least four times.

S. Fill the syringe with air, reattach to stopcock, and push on the syringe plunger to force air through the handpiece. Disconnect the syringe.

T. Repeat step S at least three times.

U. Sterilize the handpiece as follows:

- ***High Vacuum (Pre-vacuum) Sterilization:*** *Wrapped for a minimum of 3 minutes at 134° C, + 0° C/+3° C.*

Aspiration Flushing

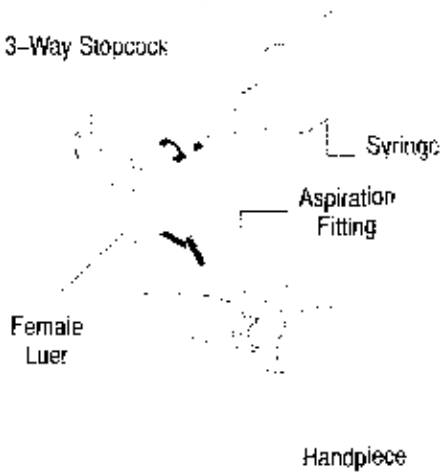


Figure 5–5. United Kingdom Flushing Set-Up.

Chapter 6

Unpacking and Setting Up

Chapter Objective: This chapter provides information for *unpacking and setting up your **Storz Millennium™ Microsurgical System**,* making necessary connections, and instructions for adding new modules.

6.1. Unpacking Instructions.

Before unpacking, inspect all packages for damage. Report any damage from shipping to the carrier. Before discarding packaging material, assure all parts are accounted for. Smaller parts may be attached to packing.

6.2. Connections and Setup.

DANGER: EXPLOSION HAZARD. Do not use in the presence of flammable anesthetics, disinfectants, aerosol sprays, or in an oxygen rich atmosphere.

The following figures show the connections for the possible configurations of the ***Storz Millennium™ Microsurgical System***. Make the connections appropriate for your configuration.

If your system includes an IV pole, the small extension should be attached at the top of the main pole, and tightened with the wing nut.

If your system includes an Illumination Module, the lamps must be installed before the module can be used. Refer to instructions in paragraph 7.4 on page 7–10.

***NOTE:** To preserve the integrity of the lamps, the Illumination Module is shipped without the lamps installed.*

Base System Set-up Without Cart.

(see figure 6-1)

A. Set the base unit on a suitable stand.

B. Set the computer unit onto the base so that the feet on the caronsel fit into the dimples in the top of the base. Make certain that the computer unit rotated 45° in either direction.

C. Connect the communications cable from the computer unit to the base unit.

D. Connect the Foot Controller cable to the other communications port on the base unit.

E. Connect the power jumper cable from the computer unit to the base unit.

F. Connect the main power cable to the computer unit and then into a medical grade wall socket. See page 8–1 for power requirements.

G. If you have the *IAV Venturi Module*, connect the air hose to the rear of the module as shown and then to an appropriate air source (see specifications on page 8–7.

H. Perform checkout prescribed in paragraph 7.1, page 7–1.

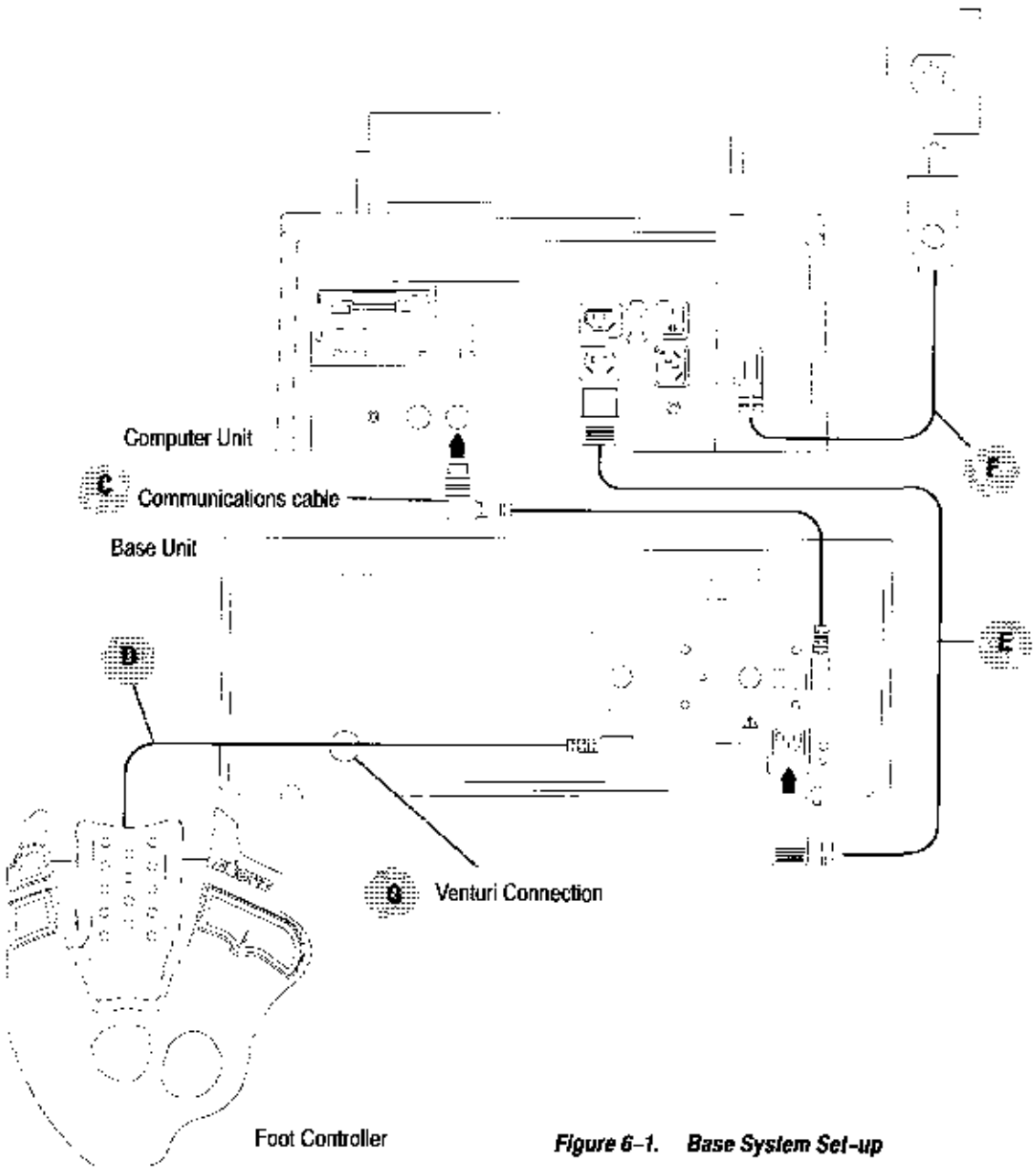


Figure 6–1. Base System Set-up

Base System with Cart Set-up. (see figure 6-2)

A. Set the base unit on the ***Storz Millennium™ Microsurgical System*** cart.

B. Set the computer unit onto the base so that the feet on the carousel fit into the dimples in the top of the base. Make certain that the computer unit rotated 45° in either direction.

C. Connect the communications cable from the computer unit to the base unit.

D. Connect the communications cable from the cart to the other communications port on the base unit.

E. Connect the Foot Controller cable to the connector inside the right (looking from front) storage area.

F. Connect the power jumper cable from the computer unit to the base unit.

G. Connect the main power cable to the computer unit and then into a medical grade wall socket. See page 8-1 for power requirements.

H. If you have the *IAV Venturi Module*, connect the air hose to the rear of the module as shown and then to an appropriate air source (see specifications on page 8–7.

I. Perform checkout prescribed in paragraph 7.1, page 7–1.

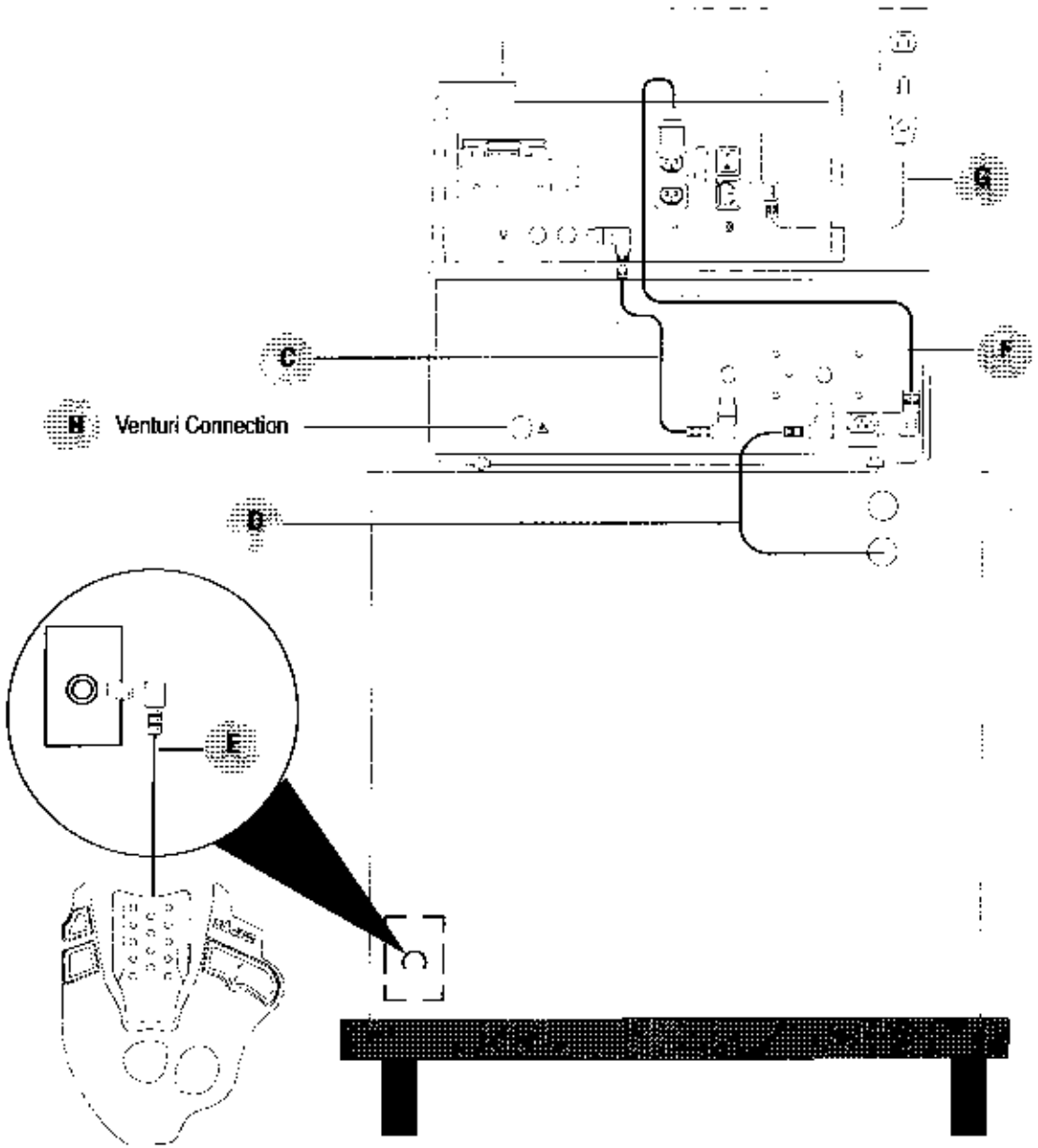


Figure 6–2. Base System with Cart Set–up.

Expanded System Set-up. (see figure 6-3)

A. Set the base unit on the *Storz Millennium™ Microsurgical System* cart.

B. Set the computer unit onto the base so that the feet on the carousel fit into the dimples in the top of the base. Make certain that the computer unit rotated 45° in either direction.

C. Use a flat blade screwdriver to release the two latches holding the front and back covers to the cart, and pop them out. Slide the expansion chassis into the cart.

D. Connect a communications cable from the computer unit to the base unit as shown.

E. Feed the communications cable which extends out of the cart back through its hole (the grommet can be pushed out) and connect it to the leftmost communications port on the expansion unit.

NOTE: The communications cables may be connected to either port on a unit without harm.

F. Connect another communications cable to the base unit and route it through the lower hole in the cart to the other communications port on the expansion unit. Reinstall the grommet.

G. Connect the Foot Controller cable to the connector inside the right (looking from front) storage area.

H. Connect a power jumper cable from the computer unit to the base unit.

I. Remove the grommet in the upper hole of the cart. Connect another power jumper cable from the computer unit to the expansion unit routing it through the hole in the cart. Reinstall the grommet.

J. Reinstall the back cover. It will snap in place.

K. Connect the main power cable to the computer unit and then into a medical grade wall socket. See page 8-1 for power requirements.

L. If you have the *IAV Venturi Module*, connect the air hose to the rear of the module as shown and then to an appropriate air source (see specifications on page 8-7.

M. Perform checkout prescribed in paragraph 7.1, page 7-1.

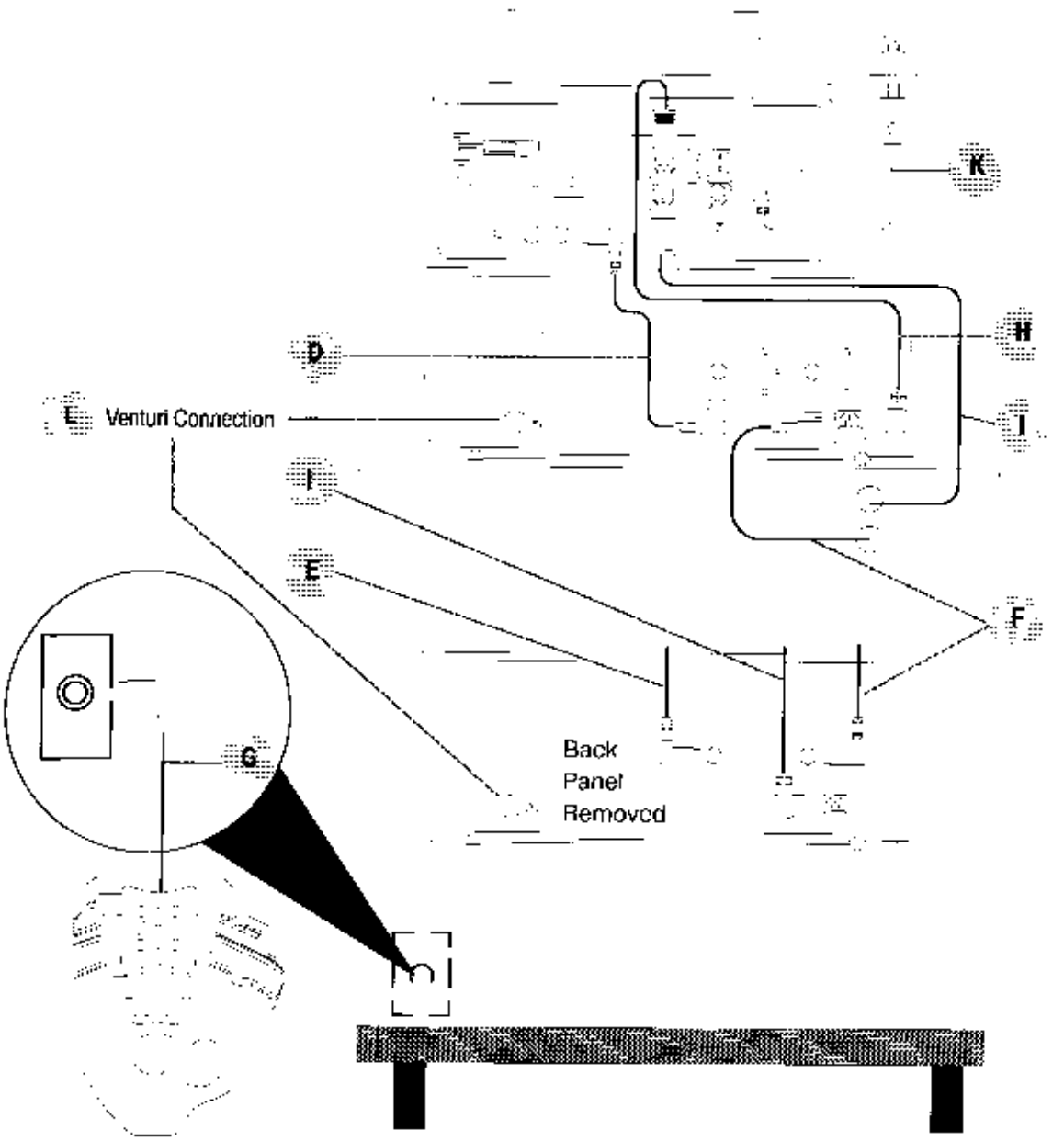


Figure 6–3. Expanded System Set–up.

6.3. Adding or Replacing Modules.

CAUTION:
Do not rotate bezel up or down when removing or inserting. Pull directly up and then out.

Refer to figure 6—4 for the following procedure:

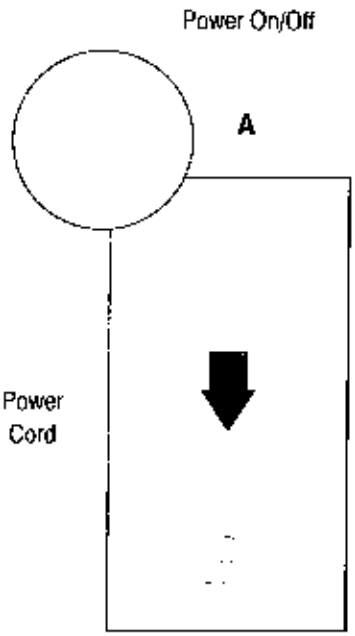
A. Turn power off and disconnect power cord from the wall socket before making any modifications. If removing a venturi module, first disconnect the air supply hose from the back of the module. If removing a power supply module, first disconnect the power cord from the back of the module.

B. With a flat blade screwdriver, loosen the two screws in the lower corners which secure the bezel to the base unit (or expansion unit). The screws are retained in the bezel. Remove the bezel by lifting up and off of the upper lip of the chassis. In the event step A was omitted, power is automatically disrupted when the bezel is removed.

C. If adding a new module, remove the filler faceplate in the space where the new module will be placed. If replacing an existing module, place fingers into recessed handle at the bottom of the module and pull outward.

D. Slide the new module into the base unit so that the slots in the module align with the guides in the base unit.

E. Push the module into the base until it stops. The connections will automatically align when the guides and slots are aligned. The front of the module should be aligned with the other modules or damage to modules may occur when bezel is installed.



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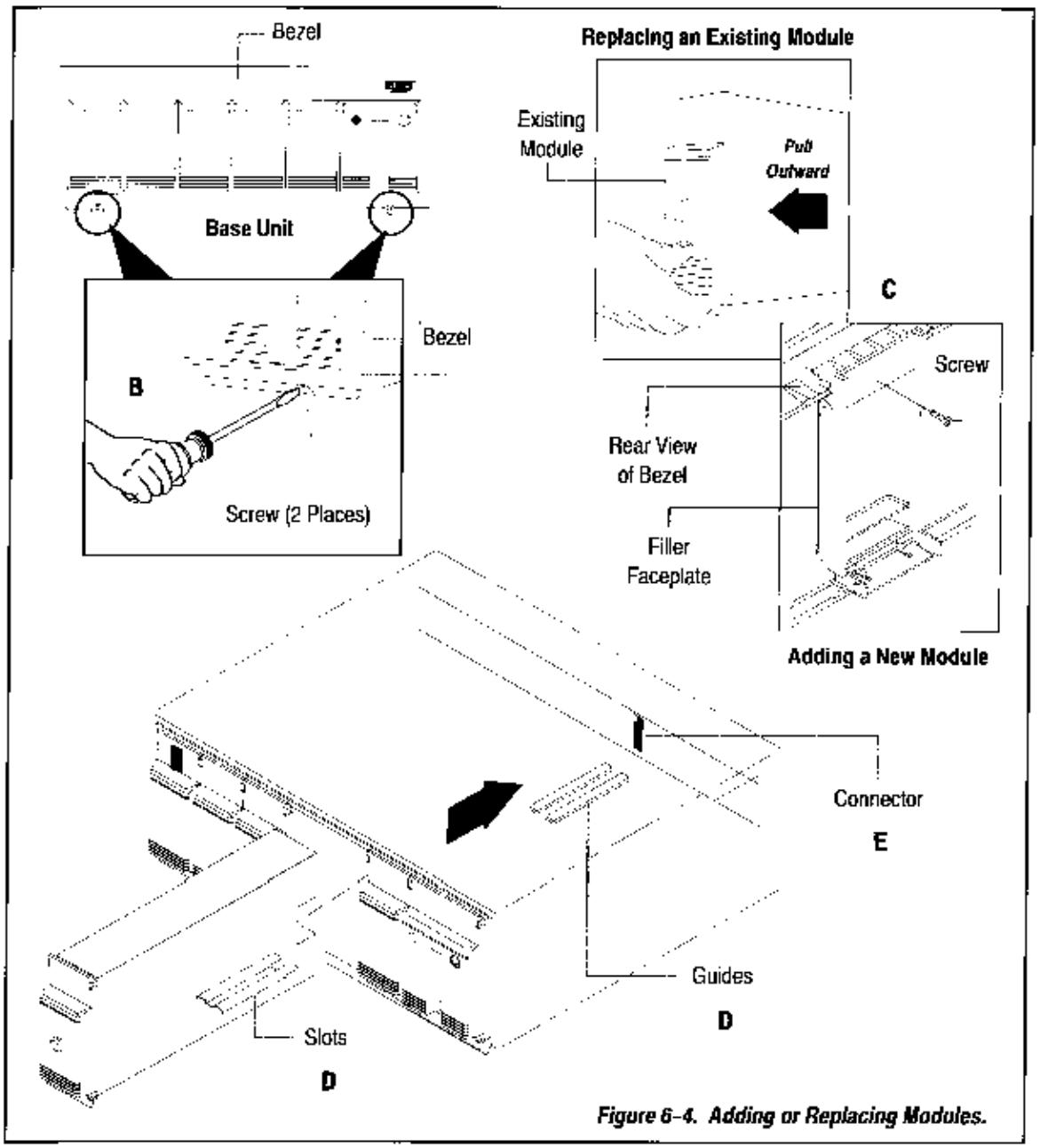


Figure 6–4. Adding or Replacing Modules.

F. Install the bezel by holding it in a vertical position as shown in Figure 6–5 and placing it on the lip at the top of the base unit while aligning the tab on the bezel with the switch opening on the power module. The switch inside the power module is spring loaded and you will feel the tension as you set the bezel into the lip.

G. Secure with the two screws loosened in step B.

H. Perform checkout prescribed in paragraph 7.1, page 7–1.

CAUTION:
Do not pivot the bezel downward from the lip on top of the base unit. Damage to the safety interlock switch may occur.

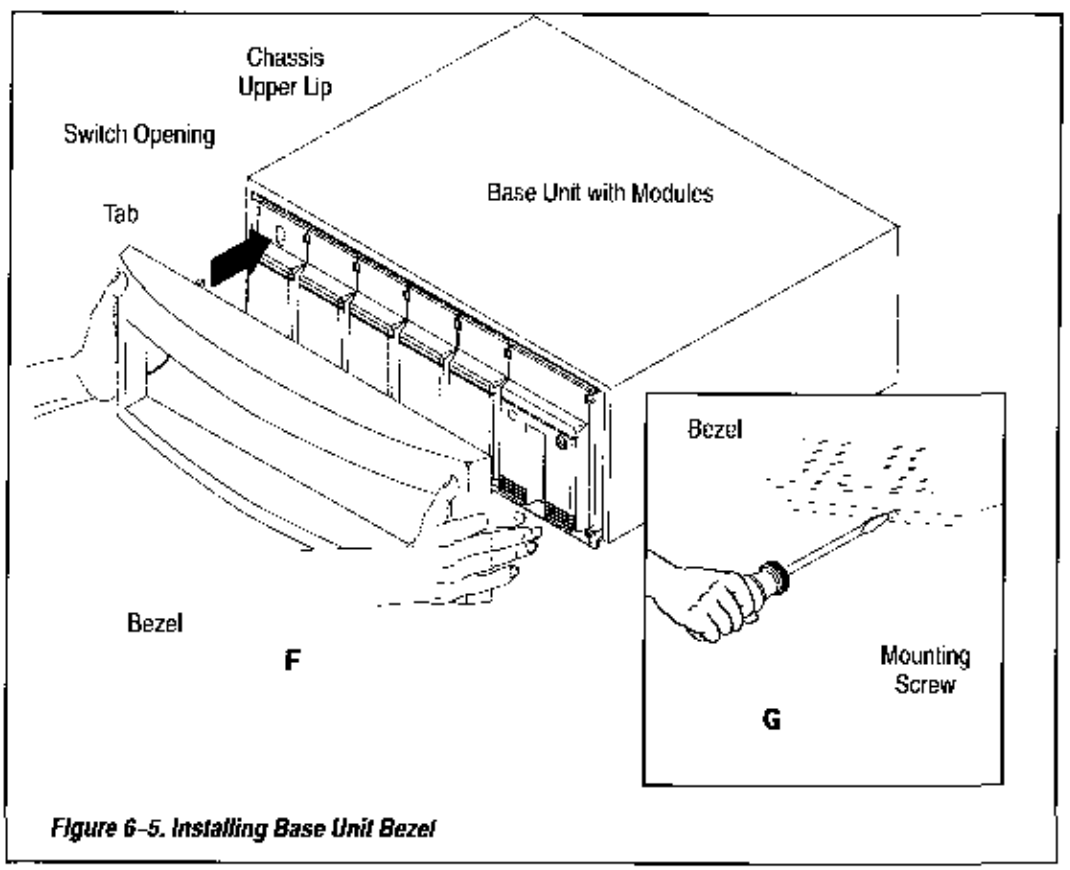


Figure 6–5. Installing Base Unit Bezel

Chapter 7

Maintenance, Service and Warranty

Chapter Objective: This chapter contains procedures for validating the operation of the ***Storz Millennium™ Microsurgical System***, introduces you to error messages which may be displayed from time to time, instructions for replacement of lamps and fuses, how to contact Storz, and warranty and environmental information.

7.1. System Checkout.

The ***Storz Millennium™ Microsurgical System*** performs a self check each time the power is turned on. The system automatically checks the system configurations for changes since the last time it was turned on. If no error message is displayed on the screen, the system is operational. **The green LED on each module indicates that the communications line between the computer unit and that module is complete.** If there was any change in the system since it was last configured, it may take up to five minutes to complete the start up routine.

7.2. User Troubleshooting.

- *If the aspiration line becomes clogged, and it cannot be cleared using reflux, remove the handpiece from the eye and use* **ASP Prime** *to clear the aspiration port of lodged material.*
- *If ultrasound calibration fails, check connections and needle, then attempt calibration a second time. If calibration fails twice, change to a known good handpiece and attempt to calibrate again. If a known good handpiece fails calibration, or if assistance is needed to determine if the original handpiece is defective, contact the Storz Instrument Company Technical Support Department (refer to paragraph 7.6 on page 7–14).*

7.3. System Messages.

All error messages displayed by the user interface are uniform in their appearance. When an error occurs, the system will sound the error tone and display a pop–up window with the error displayed. The pop–up window will provide the user with a choice of options for proceeding from the error. Nothing else may be done while a pop–up window is displayed. The figure below shows the standard error message window.

Table 7–1. Error and Warning Messages

#	Display	Meaning	Action required
1	NONE	*Unused*	
2	APPLICATION COMPONENT ERROR CODE:	*The stored and current checksums do not agree.*	Technical assistance is required (see page 7–14).
3	NONE	*Unused*	
4	BULB IN LAMP1 BURNED OUT	*Lamp 1 bulb has burned out.*	Replace bulb or press OK and change bulb later.
5	BULB IN LAMP2 BURNED OUT	*Lamp 2 bulb has burned out.*	Replace bulb or press OK and change bulb later.
6	NONE	*Unused*	

#	Display	Meaning	Action required
7	**IAV MODULE NOT CALIBRATED**	*Missing or lost factory calibration.*	Technical assistance is required (see page 7 14).
8	**NONE**	*Unused*	
9	**FILE IS NOT USABLE**	*The file being loaded is not compatible with the current microsurgical system setup*	Use Default Setup, or select Quit.
10	**MODE CHANGE NOT ALLOWED WHILE OPERATING**	*A Mode change is commanded while performing a non–irrigation operation with the footpedal.*	Disengage foot pedal and press the OK button.
11	**ALL SECONDARY WINDOWS ARE FULL, REMOVE UNNEEDED WINDOWS**	*You attempted to display a fifth function on the display.*	Remove a window which is not currently needed and press OK.
12	**COAGULATION OVERVOLTAGE**	*An overvoltage condition was detected.*	Technical assistance is required (see page 7 14).
13	**COAGULATION ACTIVITY ERROR**	*An error occurred within the coagulation module.*	Cease current activity.
14	**LAMP FAN FAILURE**	*Internal fan ceased operating.*	Technical assistance is required (see page 7 14).
15	**ASPIRATION LINE FAULT**	*Insufficient air pressure detected.*	Check air pressure and connections.
16	**CASSETTE NEAR FULL**	*The collection cassette is approximately 90% full.*	Cassette should be changed at this point, or as soon as patient safety permits.

#	Display	Meaning	Action required
17	CASSETTE IS FULL	*The collection cassette is full. While this message is displayed the aspiration function will cease to operate.*	Replace the collection cassette to continue.
18	ULTRASOUND HANDPIECE NOT CALIBRATED	*The ultrasound handpiece has not been calibrated.*	Press the U/S calibrate button.
19	NO MODE SEQUENCE IS AVAILABLE	*A mode sequence was selected but none is programmed.*	Select next mode manually. Program Doctor's file for desired mode sequence selections.
20	NETWORK DATABASE ERROR	*A data directory needed by the system is missing.*	Technical assistance is required (see page 7–14).
21	NETWORK INTERFACE CARD FAILED TO COMMUNICATE	*The computer interface card or libraries did not initialize successfully.*	Check installation, reboot and try again. If it fails again, technical assistance is required (see page 7–14).
22	NONE	*Unused*	
23	NO FOOTPEDAL IS PRESENT	*The system is not detecting the Foot Controller.*	Turn off machine and install foot controller. Check connections.
24	THE DOCTOR SETTINGS FILE IS INVALID	*The Doctor's file is not compatible with the current microsurgical system setup.*	Use Default Setup, or select Quit.
25	EXIT NOT ALLOWED WHILE OPERATING	*You can not exit while a tool is active.*	Complete all tasks before pressing the Exit button.

#	Display	Meaning	Action required
26 TO 32	**MODULE HAS LOST COMMUNICATIONS**	*A module installed in the system has lost communication with the host unit*	The system allows the user to continue (with user confirmation) depending upon the module which has lost communication (see page 7–1).
33	**IV POLE HAS LOST COMMUNICATIONS**	*The IV Pole has lost communication with the host unit*	The system allows the user to continue (with user confirmation)
34	**INCORRECT CASSETTE TYPE**	*An anterior/posterior aspiration mode has been selected and a posterior/anterior collection cassette is has been inserted.*	Insert the correct cassette or deselect the Aspiration mode
35	**INVALID ENTRY**	*Entered data must be between limits indicated.*	Enter correct data.
36 TO 42	**MODULE HAS RESET**	*An internal reset has occurred.*	None. Press OK button.
43	**IV POLE HAS RESET**	*An internal reset has occurred.*	None. Press OK button.
44	**SETTINGS FILE NOT COMPATIBLE WITH CURRENT MACHINE CONFIGURATION**	*The selected file is not compatible with the current microsurgical system setup.*	Use Default Setup, or select Quit.
45	**SCROLL MODULE NOT PRESENT ALL ASPIRATION MODES DISABLED**	*A user file which requires the scroll module was loaded but none is installed in the machine.*	Turn off machine and install module.

#	Display	Meaning	Action required
46	VENTURI MODULE NOT PRESENT ALL ASPIRATION MODES DISABLED	*A user file which requires the venturi module was loaded but none is installed in the machine.*	Turn off machine and install module.
47	MODE SEQUENCE HAS BEEN DISABLED	*A required module for the sequence is missing so the entire sequence is disabled.*	Select next mode manually. Program user file for desired mode sequence selections.
48	STARTUP MODE IS INVALID	*The programmed startup mode requires a module that is not present.*	Make another selection.
49 TO 56	INCORRECT MODULE	*A module was swapped, and an incorrect module was installed.*	Technical assistance is required (see page 7–14).
57	INCORRECT COMPONENT VERSION	*A module was swapped, and an incorrect module was installed.*	Technical assistance is required (see page 7–14).
58	ULTRASOUND OVERCURRENT	*An overvoltage condition was detected.*	Technical assistance is required (see page 7–14).
59	ULTRASOUND FAN FAILURE	*Internal fan ceased operating.*	Technical assistance is required (see page 7–14).
60	CANNOT MODIFY THE MILLENNIUM DEFAULT SETTINGS FILE	*This file cannot be modified by the user.*	Create a new doctor file for the parameters needed.
61	IOP NOT CALIBRATED	*Missing or lost factory calibration.*	Technical assistance is required (see page 7–14).

#	Display	Meaning	Action required
63	FORCEPS NOT PRESENT	*The handpiece is not detected by the system.*	Connect scissors handpiece with correct tip installed. Check connections.
64	STORZ REGISTRY PROBLEM	*An R/W error has occurred with the windows registry.*	Technical assistance is required (see page 7–14).
65	INCORRECT CD OR CD NOT PRESENT	*User tried to run a CD not supplied by Storz.*	Insert the correct CD into drive.
66	PROBLEM READING/WRITING TO FLOPPY DISK. ENSURE DISK IS INSTALLED IN FLOPPY DRIVE, WRITE PROTECT OFF FOR WRITE OPERATION AND FILE DOES NOT ALREADY EXIST	*The system cannot access the floppy disk drive. This may indicate a floppy disk read/write error occurs. The operation being performed will be aborted.*	Try another disk if a write error. The operation is aborted when the Quit Push button is depressed. The operation is retried when the Retry Push button is depressed.
67	FILE NOT DELETED	*User tried to delete a file but was unsuccessful.*	No user recourse.
68	VERIFY YELLOW CASSETTE IS INSERTED	*This message is displayed whenever posterior aspiration mode is entered.*	Assure a posterior collection cassette with a yellow insert is installed and re-insert it.
69	ULTRASOUND CALIBRATION HAS FAILED	*The ultrasound handpiece has failed its calibration*	Recalibrate or try a new handpiece.
70	PLEASE INSERT CASSETTE	*Aspiration mode is entered and no cassette is present.*	Insert the correct cassette or deselect aspiration mode.

#	Display	Meaning	Action required
71	FEATURE IS CURRENTLY UNAVAILABLE	*A feature was selected that is not part of the current configuration.*	None. Select another feature.
72	STORZ BOARD VIRTUAL DEVICE DRIVER MISSING	*The VD file is not installed on the machine.*	Technical assistance is required (see page 7–14).
73	THE CHANGES WILL NOT TAKE EFFECT UNTIL THE MACHINE IS RESTARTED	*Power to the machine needs to be cycled for the configuration file to be updated.*	Turn power off. Wait a minute and turn it on again. It may take up to 5 minutes for system to update itself.
74	THE SYSTEM IS GOING TO SHUTDOWN DUE TO APPLICATION ERROR	*A component of the computer unit has detected an error.*	Try another setting file. If error persists, technical assistance is required (see page 7–14).
75	UTILITIES SHALL EXIT DUE TO APPLICATION COMPONENT ERROR	*The setting program has detected a component error.*	Settings will be unavailable. Try another doctor file. Technical assistance may be required (see page 7–14).
76	ULTRASOUND PROBE NOT PRESENT	*The system does not detect an ultrasound handpiece*	Connect the handpiece or check connections.
77	NETWORK MANAGEMENT FAILED.	*A module installation or removal failed.*	Check installation, reboot and try again. If it fails again, technical assistance is required (see page 7–14).

#	Display	Meaning	Action required
78	**NETWORK BINDING FAILED**	*Module to module communication link could not be created.*	Check installation, reboot and try again. If it fails again, technical assistance is required (see page 7–14).
79	**A MODULE HAS FAILED TO INSTALL**	*The module has been detected, but communication could not be established.*	Check installation, reboot and try again. If it fails again, technical assistance is required (see page 7–14).
80	**NONE**	*Not used at this time.*	
81	**NONE**	*Not used at this time.*	
82 TO 87	**USAGE ERROR**	*Unknown usage error for module.*	Technical assistance is required (see page 7–14).
88	**NONE**	*Not used at this time.*	
89	**SURGICAL MODE SHALL EXIT DUE TO COMPONENT ERROR**	*An internal component error has occurred.*	Try using the default file or another user file.
90	**PROGRAMMING MODE SHALL EXIT DUE TO COMPONENT ERROR**	*An internal component error has occurred.*	Try using the default file or another user file.

7.4. Lamp Replacement.

Order replacement lamp number CX9510. Refer to figure 7-1 for the following steps.

A. To gain access to Lamp:

1. Remove the bezel (see page 6-8) and slide module out of base about six inches to expose the lamp housing cover.
2. Use a small flat blade screwdriver to loosen 2 screws fastening the lamp housing cover to the module. Screws are self retaining and cannot be removed from cover.
3. Remove cover.

B. To remove lamp:

1. While holding on to lamp near connector, remove retaining clip holding failed lamp by sliding it out from lamp mount.
2. Remove lamp from lamp mount and disconnect lamp from cable.

C. To install new lamp:

1. Connect lamp to cable (see figure 7-1, detail A).
2. Replace lamp into lamp mount, using pin to orient lamp in lamp mount.
3. While holding lamp in place, replace retaining clip into place by sliding clip into slots on side of lamp mount. Ensure both sides of clip are seated in slots provided on the lamp mount.
4. Replace module cover.

NOTE: *The lamp is a snug fit in its base.*

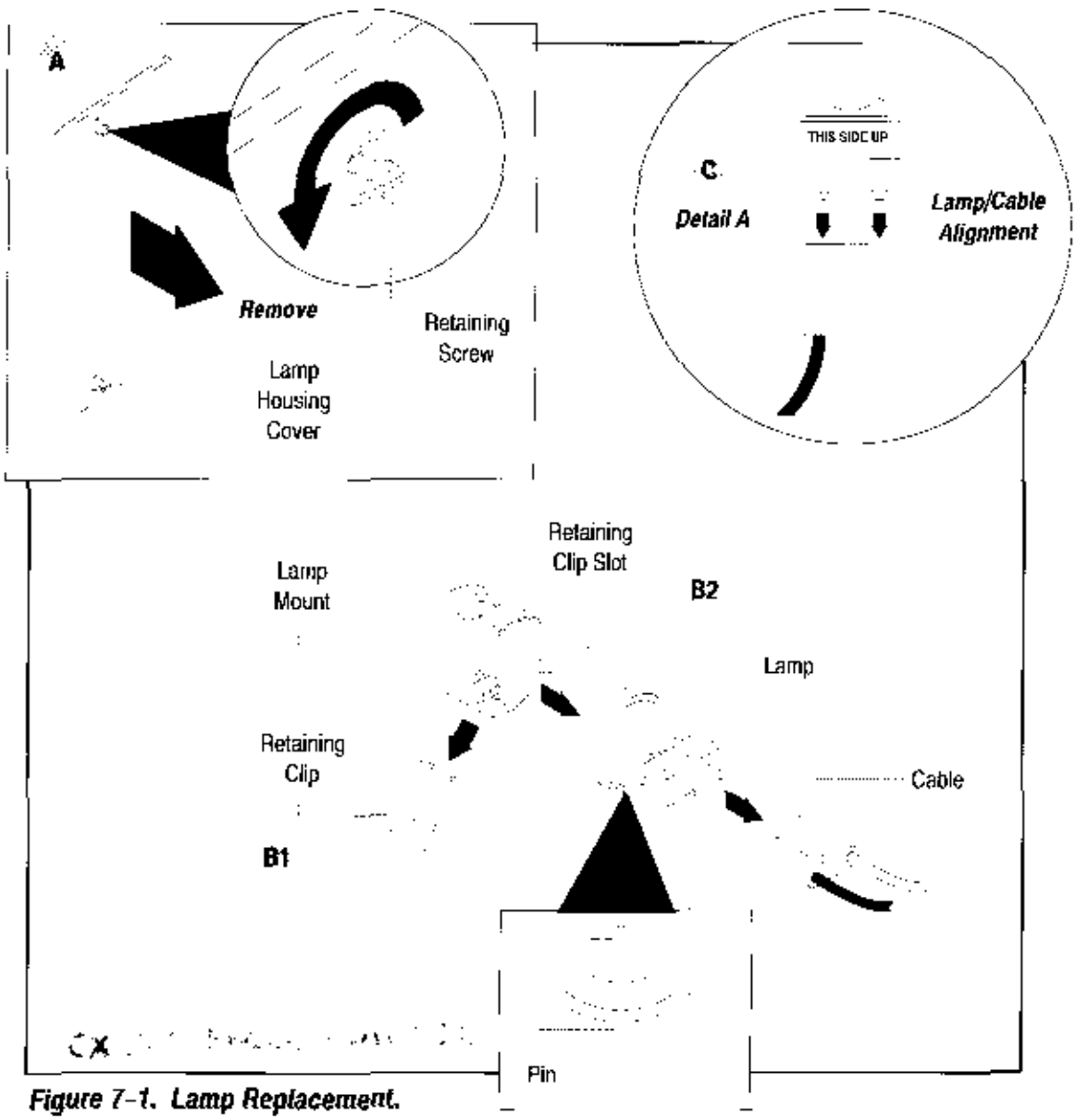


Figure 7-1. Lamp Replacement.

7.5. Fuse Replacement.

The Universal Power Entry Modules on the computer unit and the power module each contain two fuses used to protect the equipment from excessive loads.

If an over–current condition should occur which opens these fuses, they should be replaced with fuses of the same value as the original fuses (see specifications table on page 8–1). To replace the fuses:

A. Disconnect the power cord.

B. To change fuse in computer unit (figure 7–2):

1. Using a flat–blade screwdriver, turn the fuse holder counter–clockwise.
2. Pry the fuse holder out as shown.
3. Remove and replace the fuses.
4. Reinstall the fuse holder, and lock it by turning clockwise.

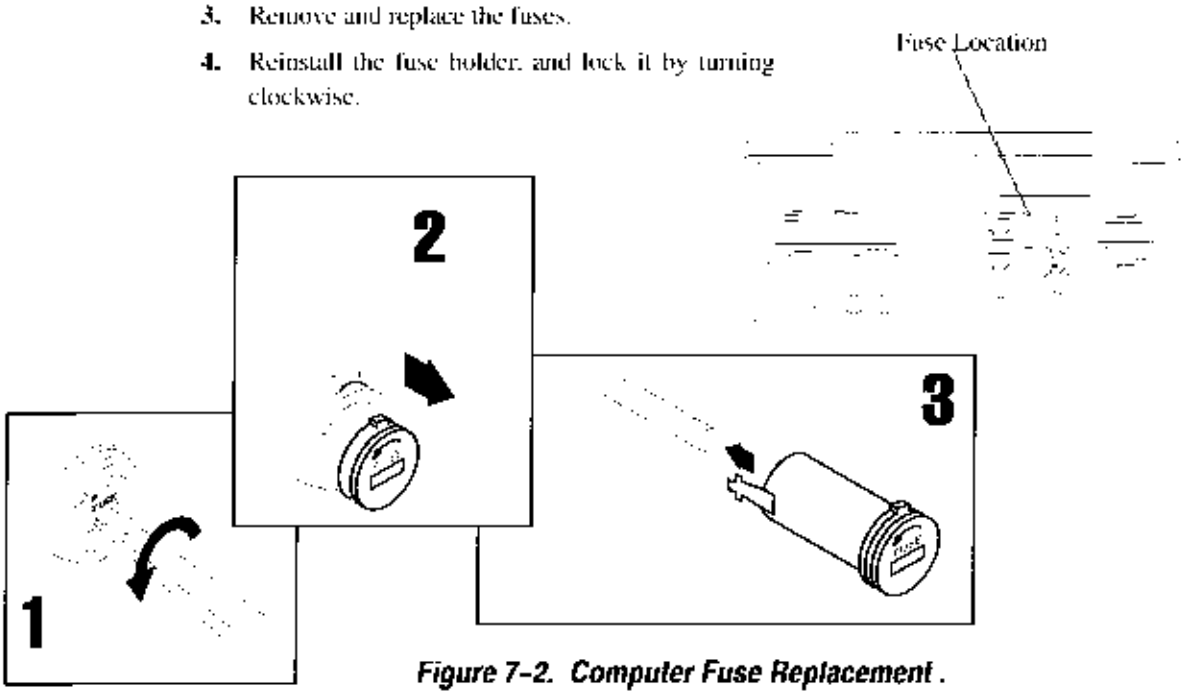


Figure 7–2. Computer Fuse Replacement .

C. To change fuse in base unit (figure 7–3):

1. Depress the tab and pull the fuse holder out.
2. Remove and replace the fuses.
3. Press the fuse holder into the housing. It will snap into the locked position.

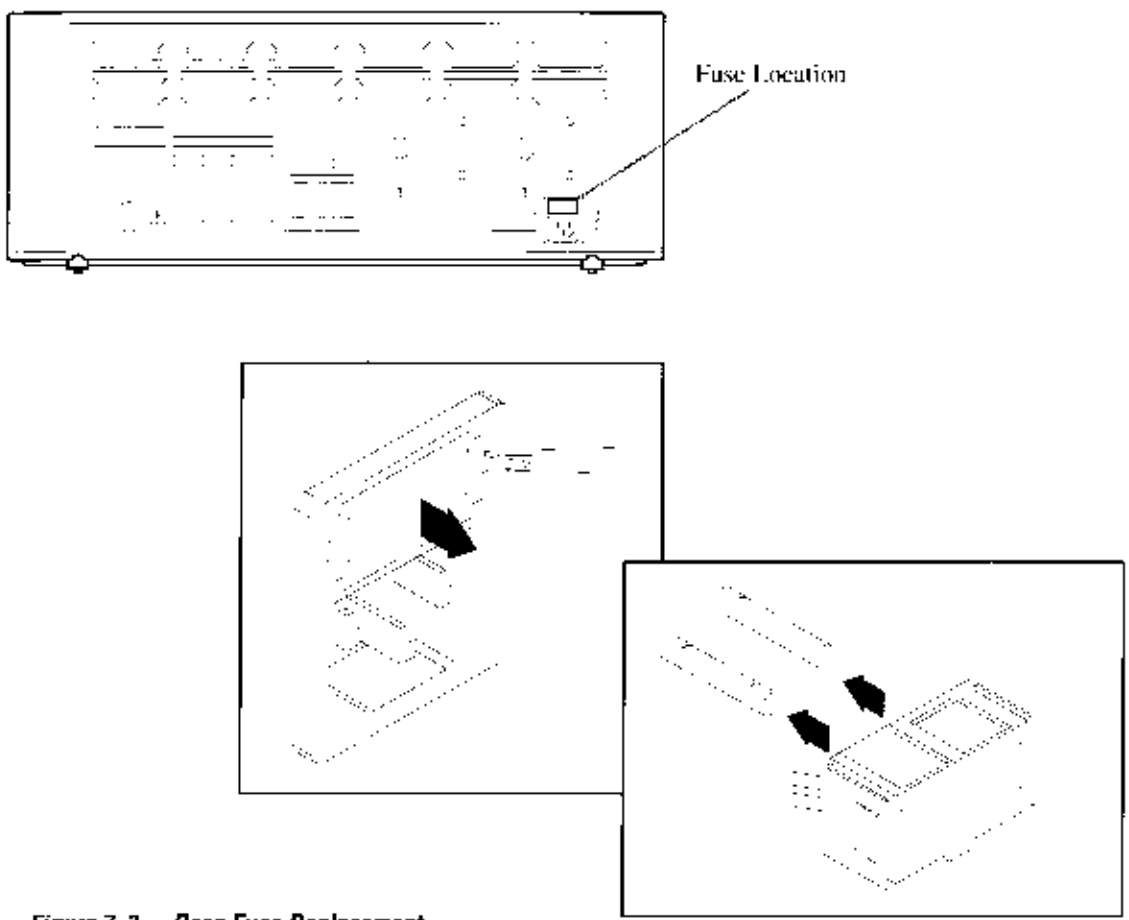


Figure 7–3. Base Fuse Replacement .

7.6. Service Information

Technical Assistance.

Assistance for ***Storz Millennium™ Microsurgical System*** is available from the Storz Technical Support Department either by phone or letter as follows:

Storz Instrument Company
3365 Tree Court Industrial Blvd.
St. Louis, Missouri 63122 U.S.A.
Attention: Technical Support Department

- *For technical support within the U.S.A. call the 24–hour telephone line 1–800–325–9510.*
- *For technical support from outside the U.S.A. either call 1–314–225–5051, send FAX to 1 314–861–3070, or contact your local Storz representative.*
- *For customer orders within the U.S.A. call 1 800 325 9500.*

Storz Instrument GmbH
Im Schuhmachergewann 4
D 69123 Heidelberg

Telephone:	06221 823 0
Technical Support:	06221 823 171
Telefax:	06221–823–167

Organize material before calling or writing for technical support. Please have the following information:

- *customer account number*
- *name of module, handpiece, etc. that needs service*
- *model number (REF #) and serial number (SN#) of the component which is located on the back panel and also on the front of ophthalmic modules but concealed by the bezel, or engraved on side of handpieces*

- *the date of purchase*
- *description of problem, listing all observable symptoms and characteristics, and details of occurrence. Was patient involved at time of occurrence?*

Returning Modules to Storz.

To return a ***Storz Millennium™ Microsurgical System*** to the Storz Instrument Company, **a return authorization number must be obtained** from the Storz Technical Support Department prior to returning any unit for repair or calibration. A written description including the following information must accompany all returned units:

A. All of the information in the paragraph above.

B. The customer name, address, and telephone number of a contact whom can be called for additional information.

C. The customer account number.

D. A description of the problem or service desired. List all observable symptoms and characteristics, and details of occurrence. Was patient involved at time of occurrence?

E. The return authorization number assigned by our Technical Support specialist (call *1 800 325 9510*).

F. Contact name and phone number if additional information is required.

Ship or otherwise return the module, transportation and insurance prepaid, to the address above.

7.7. Environmental Protection.

Accessories such as disposable packs, handpieces, and tubing will be contaminated with human tissue fragments and bodily fluids during the surgical process. These should be handled and disposed of in accordance with current hospital procedures.

The cart, irrigation/aspiration modules and foot controller may, in use, become contaminated with fluids from the operating field and should also be treated as biohazardous waste.

All major components of the system should be disposed of in accordance with techniques for disposal of standard electronic components and equipment.

7.8. Warranty Information.

Storz warranty information is included on each invoice. Please consult the invoice for specific warranty terms and condition. In the event of a malfunction or for assistance with a warranty claim, contact one of the offices listed on page 7 14.

Chapter 8

Specifications

8.1. Environmental and Physical Specifications

Environmental Specifications

Parameter	Specifications
Electrical Input	Detachable international power cord Universal Input (100 240 VAC, 50/60 Hz) Equipotential grounding stud Fuse part number CX9520.
Pneumatic Input (Venturi Module)	5 bar to 8 bar 550 kPa to 790 kPa 80 psi to 115 psi
Temperature	Ambient Operating Temperature: 10° to 40° Celsius (50° to 104° Fahrenheit) Ambient Storage and Transit Temperature: −20° to 60° Celsius (−4° to 140° Fahrenheit)
Humidity	Operating Humidity: 30% to 70% Relative Storage and Transit Humidity: 10 to 98% Non−Condensing
Altitude	Operates as rated up to 5,000 feet above sea level
Shock/Vibration	Passes NAVMAT−P9492 Passes MIL−STD−810D Passes MIL−STD−202 Passes NSTA Schedule 2A
Noise	Less than 60 decibels (A Scale) @ 1 meter

Physical Specifications

Parameter	Specifications
Computer and Base Unit	51 cm (H) x 51 cm (W) x 51 cm (D) 20 in. (H) x 20 in. (W) x 20 in. (D)
Instrumentation Cart	86 cm (H) x 61 cm (W) x 53 cm (D) 34 in. (H) x 24 in. (W) x 21 in. (D)
Agency certifications	ETL listed to UL2601 CSA listed to C22.2 No. 601 -1 M90 Complies with IEC 601-1 and IEC 601-2-2 JIS approved

Equipment Classifications

Type of Protection Against Electrical Shock	Class I
Degree of Protection Against Electrical Shock	Type BF
Degree of Protection Against Water Ingress	Ordinary
Mode of Operation	Continuous
Electromagnetic Compatibility (EMC)	Class A

8.2. Ophthalmic Module Specifications

Air/Fluid Exchange Specifications

NOTE: This is part of the Scissors/Air Module.

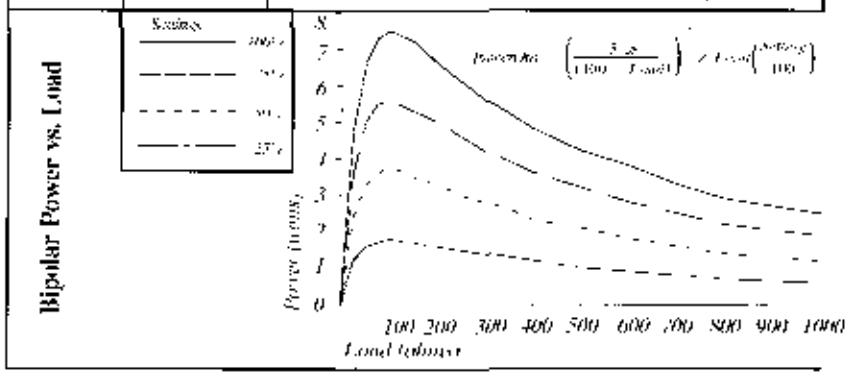
Parameter	Specification
Input	Utilizes room air through a 0.22 micron hydrophilic filter
Pressure	100 mmHg maximum air pressure, flow rates up to 3.5 standard cubic feet (99 liter) per hour
Safety	System includes pneumatic receiver and shut–off valve in case of power loss System will detect and sound audible warning for over/under–pressure conditions

Scissors/Forceps Specifications

NOTE: This is part of the Scissors/Air Module.

Parameter		Specification
Output		Single Scissors/Forceps, Floating BF Connection Electrical control only, no manual override
Modes of Operation		Linear Cut Rate Mode Fixed Cut Rate Mode Single Cut Mode Proportional Activation Mode
Operational Parameters	Linear Cut Rate Mode	Range: 30 to 300 cuts per minute in 1 cut per minute increments Control: Linear control of cut rate via the foot pedal
	Fixed Cut Rate Mode	Range: 30 to 300 cuts per minute in 30 cut per minute increments Control: On/Off control via the foot pedal
	Single Cut Mode	Range: Single Cut Control: Close/Open one time when the foot pedal is depressed
	Proportional Activation Mode	Controlled from rocker switch on foot pedal. Right rocker drives motor forward to close tip and left rocker reverses it to open tip. The motor stops in its current position when switch is released.

Coagulation Module Specifications

Parameter		Specification
Coagulation Connections	Connector	Single, Floating BF Connection Coaxial connector
	Cords	United States Banana Jack Cord, Banana Jack to Coaxial adapter International – Reusable Coaxial Cord
Modes of Operation		Linear Mode – Fixed Mode
Operating Parameters	Linear Mode	Output Range: 7.5 Watts Nominal @ 100 ohms Maximum Peak Open Circuit Voltage = 120 Range: Programmable from 0% to 100% in 1% increments Control: Linear control of coagulation power via the foot pedal
	Fixed Control	Output Range: 7.5 Watts Nominal @ 100 ohms Maximum Peak Open Circuit Voltage – 120 Range: Programmable from 0% to 100% in 1% increments Control: On/Off control via the foot pedal
Bipolar Power vs. Load		

Illumination Module Specifications

Parameter		Specification
Connections		Two ACMI compatible ports
Modes of Operation		Independent illumination and control of either port Simultaneous illumination of both ports
Operation Parameters		Lamp Life: 500 hours minimum
Luminous Output	Intensity	Maximum light output from a single port approximately 61.8 Candela/mm^2 (Std. Dev. 8.5 Candela/mm^2
	Filtering	Transmission approximately between 400 nm and 750 nm
	Control	Independent on/off and low/medium/high control
	Ultra High Output	Equal to approximately 100% of maximum lumens
	Extra High Output	Equal to approximately 75% of max. lumens
	High Output	Equal to approximately 50% of max. lumens

Irrigation, Venturi Aspiration and Vitrectomy Module Specifications

Parameter		Specification
Aspiration	General	Provides Cassette Full and Near–Full Sensing Programmable Rise time curves
	Connection	Standard Snap–Tite pneumatic coupler
	Air Source	Filtered medical grade air or medical grade nitrogen input between 80 to 100 psig., with a dew point of 35°F (1.6°C), be oil–free, aerosol particle filtered and solid particle filtered to 5 microns
	Modes of Operation	Linear control of aspiration Fixed, On/Off control of aspiration
	Operating Parameters	Frag: 15 mmHg to 400 mmHg I/A mode: 5 mmHg to 550 mmHg Phaco: 15 mmHg to 250 mmHg Vitrectomy: 5 mmHg to 550 mmHg Control: 1 mmHg increments at rated input gas pressure of 80 to 100 psig. Derated operation down to 60 psig
Irrigation		Gravity feed from I/V bottle with pinch valve On/Off control via foot pedal
Reflux	Control	Activated via foot control
	Safety	Automatic detection of anterior and posterior cassettes

Irrigation, Venturi Aspiration and Vitrectomy Module Specifications (continued)

Parameter		Specification
Vitrectomy	Linear Cut Rate Mode Operating Parameters	Range: 30 to 750 cuts per minute in 1 cut per minute increments Control: Linear control of cut rate via the foot pedal
	Fixed Cut Rate Mode Operating Parameters	Range: 30 to 750 cuts per minute in 1 cut per minute increments Control: On/Off control of cur rate via the foot pedal
	Single Activation Mode Operating Parameters	Range: Single Cut Control: Close/Open activation when the foot pedal is depressed

Ultrasound Module Specifications

Parameter		Specification
Special Features		Ultrasound Time: System will record and display ultrasound time in 1 second increments Calibration: System will provide one step calibration Probe Present: System will provide a probe present detection system
Connection		Type: Floating BF Connection White band/dot indicates phacoemulsification Yellow band/dot indicates phacofragmentation
Modes of Operation		Linear ultrasound/Frag Mode Pulsed ultrasound Mode
Operating Parameters	Linear Ultrasound Mode	Power: 35 Watts @ approx. 1500 ohms Frequency: Single Frequency: 28.5 kHz Range: 0% to 100% of maximum power in 1% increments Control: Linear power control via the foot pedal Other: Power will have linear ramp up from zero when first activated via the foot pedal
	Pulsed Ultrasound Mode	Power: 35 Watts @ approx. 1500 ohms Frequency: Single Frequency: 28.5 kHz Range: 1 to 20 pulses per second in 1 pulse increments Control: Pulse ultrasound activation via the foot control

IV Pole Specification

Parameter		Specification
General		Automated Provides two (2) bottle hooks Integrated into Ophthalmic Cart
Operation Parameters	Capacity	Capable of lifting two 500 cc glass bottles of balanced salt solution
	Travel	From cassette height up 100 cm. (39.4 in.)
	Speed	6.0 cm/sec. (2.5 in./sec.)
	Control	Controlled via touch screen entry, remote, or foot control
	Positioning	Relative from home sensed position

Computer Unit Specifications

Parameter		Specification
Display Assembly	Display	Technology: Flat Panel. Liquid crystal display (TFT LCD) full color Size: 10.4" diagonal Pixels: 640 x 480 **Physical Adjustment:** Tilt: +15° up and −10° down Brightness: Controlled via knob on rear of computer unit.
	Touch Screen	Technology: Resistive Analog Size: Approximately 10.4" diagonal active area Environmental: Chemical resistant to sterilizing solutions Waterproof bezel
Computer Assembly	Motherboard	Technology: IBM Compatible, 486 or better
	Computer hardware	3.25" Floppy Drive CD ROM Drive Hard Drive Two Audio Speakers

Remote Control Unit Specifications

Parameter		Specification
General		Wireless pointing device providing line of sight operation using an IR transmitter Provides operation up to 15 feet from display console Powered from standard AA battery(s) Low battery indicator Splash–proof
Remote Functions	Coagulation Power (COAG)	Increment Decrement
	Ultrasound Power (U/S)	Increment Decrement
	Aspiration (ASP)	Increment Decrement
	IV Pole	Up Down
	Mode	Increment Decrement
	Illumination (ILUM)	On/Brighten Off/Dim

Foot Controller Specifications

Parameter		Specification
General		External components/housings are corrosion resistant Watertight housing Corded, low voltage connection to computer unit Non skid base One blue colored switch for coagulation power One gray colored function switch One gray colored rocker switch
Modes of Operation		
Center Pedal	Pitch	Linear On/Off
	Yaw	Left On/Off (simulated) Right On/Off (simulated) Left Linear Right Linear
Right Rocker Switch		Increase/Decrease On/Off
Left Push–buttons (2)		Coagulation (blue) Function (gray)
Operational Parameters		
Center Pedal	Pitch	Motion: Pitch (Up/Down), Automatic return to up position Detent: (2) Programmable as to position and resistance Control: Provides primary linear function or on/off control

Foot Controller Specifications (continued)

Parameter		Specification
Center Pedal (continued)	Yaw	Motion: Yaw (Left/Right), Automatic return to center Detent: (1) Center Detent, Non–programmable Control: Provides secondary linear function in primary yaw direction and on/off control in secondary yaw direction
Right Rocker Switch		Motion: Momentary Toggle Control: Provides increment/decrement or on/off control of assigned function
Left Push–button Switches (2)		Motion: Momentary Push–button Control: 1 switch provides on/off control of coagulation power (blue color), 1 switch with programmable function

INDEX

A

Agency Certifications 8–2
Air/Fluid Exchange
  Module
    Description, ... 1–2, 4–53
    Specifications, ... 8–3
  Operation, ... 4–53
  Setup, ... 4–53, 4–54
Anterior Surgery, User
    Interface, ... 2–6
Aspiration
  See also I/A Vitrectomy
      Module
  Handpiece
    Cleaning, ... 5–3
    Sterilization, ... 5–5
  Operation
    Venturi, ... 4–8
Assistance, ... 7–14
Audio Control, ... 3–8

B

Base Unit, Operation, ... 4 4
Bipolar. *See* Coagulation
Bottle Infusion
  Operation, ... 4–56
  Setup, ... 4–56

C

Cabinet, Cleaning, ... 5–1
Calibration
  None Required
Capsule Polish, Operation
  Venturi, ... 4–9
Cart, Description, ... 4–5
Checkout, System, ... 7 1
Cleaning
  Approved Substances, . 5–1
  Cabinet, ... 5–1
  Handpiece
    Bipolar Accessories, . 5–2
    For U.K., ... 5–18
    Irrigation/Aspiration, . 5–3
    Phacoemulsification, . 5–6
    Phacofragmentation, 5–11
    Scissors, ... 5–15
    Vitreoretinal Instruments,
        5–16
Coagulation
  Accessories
    Cleaning, ... 5 2
    Setup
      Fixed, ... 4–44
      Linear, ... 4–46
  Module
    Description, ... 1–2, 4–43
    Specifications, ... 8–5
  Operation, ... 4–43
Computer Unit
  Description, ... 1–2
  Operation, ... 4–1
  Specifications, ... 8–11
Connections, Electrical, .. 6–1
Controls and Indicators. *See*
    Operation: Control

Customizing
Audio Control, ... 3–8
Foot Pedal, ... 3–6
Language, ... 3–11
Setup Mode, ... 3–1, 3–5
Create New, ... 3–1
Modify, ... 3–3, 3–7

D

Description
Cart, ... 4–5
Foot Controller, ... 1–3
IV Pole, ... 4–6
Module
Air/Scissors, ... 4–50
Bipolar Coagulator, . 1–2, 4–43
Computer Unit, ... 1–2
I/A Vitrectomy
Venturi, ... 1–2, 4–8
Illumination, ... 1–3, 4–48
Scissors, ... 1–3, 4–50
Ultrasound
Phacoemulsification, ... 1–3, 4–28
Phacofragmentation, ... 1–3, 4–28
Viscous Fluid System, ... 4–58
System, ... 1–1
Disposables, Set–Up, and Use
Coagulation
Fixed, ... 4–44
Linear, ... 4–46
Irrigation/Aspiration
Venturi, ... 4 12
Microscissors, ... 4–51
Phacoemulsification
Venturi, ... 4–43
Phacofragmentation
Venturi, ... 4–38
Viscous Fluid System, 4–60
Vitrectomy
Anterior
Venturi, ... 4–18
Posterior
Venturi, ... 4–23
Dual Linear Control,
Description, ... 2–12
Operation, See Ultrasound

E

Environmental Protection, 7–16
Equipment Classifications, 8–2
ErgoTec. *See* Vitreoretinal Instruments
Error Messages, ... 7–2

F

Foot Control
Customizing, ... 3–6
Description, ... 1–3, 2–9
Functions
Button, ... 2–10

Foot Control (continued)
Functions continued)
Linear Control, ... 2–12
Operation
Aspiration
Venturi, ... 4–10
Irrigation
Venturi, ... 4–10
Ultrasound, .. 4–30, 4 31
Vitrectomy
Venturi, ... 4–16
Specifications, ... 8–13
Fragmentation. *See* Phacofragmentation
Fuse, Replacement, ... 7–12

H

Handpiece
Cleaning
Bipolar Accessories, . 5–2
For U.K., ... 5–18
Irrigation/Aspiration, . 5–3
Phacoemulsification, . 5 6
Phacofragmentation, 5–11
Scissors/Forceps, .. 5–15
Vitreoretinal Instruments, ... 5 16
Sterilization
Bipolar Accessories, . 5–2
For U.K., ... 5· 18
Irrigation/Aspiration, . 5–5
Phacoemulsification, 5–10
Phacofragmentation, 5–14
Scissors/Forceps, .. 5–15
Vitreoretinal Instruments, ... 5–16

I

I/A
Handpiece
Cleaning, ... 5–3
Sterilization, ... 5–5
Operation
in Phacoemulsification mode, ... 4–29
in Phacofragmentation mode, ... 4–29
I/A Vitrectomy
Module
Description
Venturi, ... 1 2, 4–8
Specifications
Venturi, ... 8–7
Operation
I/A
Venturi, ... 4–8
Vitrectomy
Venturi, ... 4–16
Setup
I/A
Venturi, ... 4–12
Vitrectomy
Anterior
Venturi, ... 4–18
Posterior
Venturi, ... 4–23

Illumination
Module
Description, ... 1–3, 4–48
Specifications, ... 8–6
Operation, ... 4 · 48
Installation,
Module, ... 6–8
Screen Drape, ... 4–3
Intraocular Pressure.
See Air Exchange or Bottle Infusion
Irrigation
See also I/A Vitrectomy Module
Handpiece
Cleaning, ... 5–3
Sterilization, ... 5–5
Operation
Venturi, ... 4–8
IV Pole
Description, ... 4–6
Specifications, ... 8–10

L

Lamp, Replacement, ... 7–10
Language, Customizing, 3–11
Legal Standards 8–2
Linear Vacuum
Operation
Phaco, ... 4–31
Sculpt, ... 4–32
Sculpt, ... 4–32
Venturi, ... 4–9
Segment Removal, ... 4–32

M

Module
Adding, ... 6–8
Air/Scissors,
See Air/Scissors
Coagulation,
See Coagulation
Computer Unit,
See Computer
I/A Vitrectomy.
See I/A Vitrectomy
Illumination.
See Illumination
IV Pole.
See IV Pole
Replacing, ... 6–8
Scissors,
See Air/Scissors
Ultrasound.
See Ultrasound Module: Phaco or Frag
Viscous Fluid System, 4–58

O

Operation
Air/Fluid Exchange ... 4–53
Aspiration
Venturi, ... 4–8
Bottle Infusion 4–56
Capsule Polish
Venturi, ... 4–9
Cataract Example, ... 1-7
Coagulation, ... 4–43
Computer Unit, ... 4–1
Conclusion, ... 1–12

Operation (continued)
Control
Numeric Keypad, ... 2–2
Option List, ... 2–1
Pop–Up Window, ... 2–3
Progress Bar, ... 2–2
Push Button, ... 2–1
Spin Button, ... 2–1
Tab, ... 2–3
Fixed Vacuum, Phaco . 4–32
Foot Control. *See* Foot Control: Operation
Illumination, ... 4–48
Irrigation
Venturi, ... 4–8
Linear Vacuum
Phaco 4–31
Venturi 4 9
Phacoemulsification, .. 4–35
Linear, ... 4–30
Pulsed, ... 4 28
Sculpt 4–32
Phacofragmentation, . 4–40
Linear, ... 4–31
Pulsed, ... 4–28
Scissors/Forceps, ... 4–50
Segment Removal 4–32
Turning On System, ... 1–5
Viscoelastic Removal .. 4–9
Viscous Fluid
Aspiration
Fixed, ... 4–59
Linear, ... 4–59
Injection
Fixed, ... 4–58
Linear, ... 4–58
Viscous Fluid System, 4–60
Vitrectomy
Anterior
Venturi, ... 4–18
Cutter Modes
Venturi, ... 4–17
General
Venturi, ... 4–16
Posterior
Venturi, ... 4–23
Yaw Aspiration, ... 4–30

P

Phacoemulsification. *See* Ultrasound
Phacofragmentation. *See* Ultrasound
Posterior Surgery, User Interface, ... 2–7

R

Reflux, ... 4–9, 4–12, 4–14, 4–17, 4–18, 4–23, 4–29, 4–33, 4–38, 7–1
Remote Control
Description, ... 4–7
Specifications, ... 8–12
Repair, ... 7–15
Replacement
Fuse, ... 7–12
Lamp, ... 7–10
Module, ... 6–8

Returns, ... 7–15

S

Save, Mode Setup, ... 3 12
Scissors
Handpiece
Cleaning, ... 5–15
Sterilization, ... 5–15
Module
Description, ... 4–50
Specifications, ... 8–4
Operation, ... 4–50
Screen Drape Installation . 4–3
Segment Removal 4–32
Setup
Air Exchange, ... 4–54
Bottle Infusion, ... 4–56
Coagulation
Fixed, ... 4–44
Linear, ... 4–46
Irrigation/Aspiration
Example, ... 1 10
Venturi, ... 4–12
Microscissors, ... 4–51
Mode
Create New, ... 3–1
Customizing, . . . 3–5, 3–7
Modify, ... 3–3
Saving, ... 3–12
Transferring, ... 3 13
Phacoemulsification
Example, ... 1–7
Venturi, ... 4–33
Phacofragmentation
Venturi, ... 4–38
Viscous Fluid System, 4–60
Vitrectomy
Anterior
Venturi, ... 4–18
Example, ... 1–11
Posterior
Venturi, ... 4–23
Specifications
Computer Unit, ... 8 11
Environmental, ... 8–1
Foot Control, ... 8–13
Module
Air/Fluid Exchange, . . 8–3
Coagulation, ... 8 5
I/A Vitrectomy
Venturi, ... 8–7
Illumination, ... 8–6
IV Pole, ... 8–10
Scissors/Forceps, . . . 8–4
Ultrasound, ... 8–9
Physical, ... 8–2
Remote Control, ... 8–12
Sterilization
See also Cleaning
Bipolar Accessories, . . . 5–2
I/A Handpiece, ... 5–5
Phacoemulsification
Handpiece, ... 5–10
Phacofragmentation
Handpiece, ... 5–14
Scissors, ... 5–15
Vitreoretinal Instruments,
. 5–16

System Checkout, ... 7–1
System Status Screen . . 2–10

T

Technical Assistance, . . . 7–14
Troubleshooting, ... 7 1

U

Ultrasound
Handpiece
Cleaning
For U.K., ... 5–18
Phacoemulsification, ... 5–6
Phacofragmentation, ... 5–11
For U.K. 5–18
Sterilization
Phacoemulsification, ... 5–10
Phacofragmentation, ... 5–14
Phacoemulsification
Module
Description, . 1–3, 4–28
Specifications, ... 8–9
Operation, ... 4–35
Fixed Vacuum . . . 4–32
Linear, ... 4–30
Linear Vacuum . . . 4–31
Pulsed, ... 4–28
Sculpt 4–32
Segment Removal 4–32
Yaw Aspiration . . . 4–30
Setup, Venturi, ... 4 -33
Phacofragmentation
Module
Description, . 1–3, 4 28
Specifications, ... 8–9
Operation, ... 4–40
Linear, ... 4 -30
Pulsed, ... 4–28
Setup
Venturi, ... 4 -38
Unpacking, ... 6–1
User Interface
Anterior Surgery, ... 2 -6
Basic Operation, ... 2–1
Controls and Indicators. *See* Operation: Control
Foot Controller, ... 2 -9
Posterior Surgery, ... 2–7
Remote Control, ... 4–7
Screen
Hierarchy, ... 2–8
Layout, ... 2–4

V

Vacuum
Fixed, Phaco, ... 4–32
Linear
I/A, ... 4 -9
Phaco, ... 4–31
Response, ... 4–10

Venturi Module. *See* I/A Vitrectomy: Venturi
Viscoelastic Removal 4–9
Viscous Fluid, Operation
Aspiration
Fixed, ... 4–59
Linear, ... 4–59
Injection
Fixed, ... 4–58
Linear, ... 4–58
Viscous Fluid System
Module, Description, . 4–58
Operation, ... 4–60
Setup, ... 4–60
Vitrectomy
See also I/A Vitrectomy Module
Operation
Anterior
Venturi, ... 4–18
Cutter Modes
Venturi, ... 4–17
General
Venturi, ... 4–16
Posterior
Venturi, ... 4–23
Vitreoretinal Instruments, Cleaning, ... 5–16

W

Warranty Information, ... 7–16